FOOD AND DRUG ADMINISTRATION

CENTER FOR TOBACCO PRODUCTS (CTP)

TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE

(TPSAC)

THURSDAY, NOVEMBER 18, 2010

1:00 p.m. to 5:15 p.m.

Food and Drug Administration Headquarters

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10903 New Hampshire Avenue

Silver Spring, Maryland

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I N D E X

P R O C E E D I N G S

(1:10 p.m.)

Call to Order

DR. SAMET: I'm Jon Samet, the chair of the Tobacco Products Scientific Advisory Committee. I guess if you're in L.A., it's good morning, and otherwise, if you're in D.C., it's good afternoon. Thank you for joining us. I want to make a few statements, and then we'll introduce the committee.

For topics such as those being discussed at today's meeting, there are often a variety of opinions, some of which are quite strongly held. Our goal is that today's meeting will be a fair and open forum for discussion of these issues, and that individuals can express their views without interruption. Thus, as a gentle reminder, individuals will be allowed to speak into the record only if recognized by the chair. We look forward to a productive meeting.

In the spirit of the Federal Advisory Committee Act and the Government in the Sunshine

Act, we ask that the advisory committee members take care that their conversations about the topics at hand take place in the open forum of the meeting. We are aware that members of the media are anxious to speak with the FDA about these proceedings. However, FDA will refrain from discussing the details of this meeting with the media until its conclusion. Also, the committee is reminded to please refrain from discussing the meeting topics during breaks. That would be hard to do today, I guess. Thank you.

So let me turn next to Caryn Cohen, our DFO, for the conflict of interest statement.

Conflict of Interest Statement

MS. COHEN: Thank you, Dr. Samet.

The Food and Drug Administration is convening today's meeting of the Tobacco Products Scientific Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. With the exception of the industry representatives, all members and nonvoting members are special government employees or regular

federal employees from other agencies, and are subject to federal conflict of interest laws and regulations.

The following information on the status of this committee's compliance with federal ethics and conflict of interest laws covered by, but not limited to, those found at 18 USC Section 208 and Section 712 of the Federal Food, Drug and Cosmetic Act is being provided to participants in today's meeting and to the public.

FDA has determined that members of this committee are in compliance with federal ethics and conflict of interest laws. Under 18 USC Section 208, Congress has authorized FDA to grant waivers to special government employees and regular federal employees who have potential financial conflicts when it is determined that the agency's need for a particular individual's services outweighs his or her potential financial conflict of interest.

Under Section 712 of the FD&C Act, Congress has authorized FDA to grant waivers to

special government employees and regular federal employees with potential financial conflicts when necessary to afford the committee essential expertise.

Related to the discussions of today's meeting, members of this committee have been screened for potential financial conflicts of interest of their own, as well as those imputed to them, including those of their spouses or minor children, and, for purposes of 18 USC Section 208, their employers. These interests may include investments, consulting, expert witness testimony, contracts, grants, CRADAs, teaching, speaking, writing, patents and royalties, and primary employment.

Today's agenda involves receiving an update on the Menthol Report Subcommittee and receiving and discussing presentations regarding the data requested by the committee on the March 30th and 31st, 2010 meeting of the Tobacco Products Scientific Advisory Committee.

DR. SAMET: Karen, are you done?

MS. COHEN: Pardon me?

DR. SAMET: That was the end?

MS. COHEN: No. I'm still going.

DR. SAMET: Okay. Sorry.

MS. COHEN: This is a particular matters meeting, during which general issues will be discussed. Based on the agenda for today's meeting and all financial interests reported by the committee members, no conflict of interest waivers have been issued in connection with the meeting. To ensure transparency, we encourage all committee members to disclose any public statements that they have made concerning the issues before the committee.

With respect to FDA'S invited industry representatives, we would like to disclose that Drs. Daniel Heck and John Lauterbach and Mr. Arnold Hamm are participating in this meeting as nonvoting industry representatives, acting on behalf of the interests of the tobacco manufacturing industry, the small business tobacco manufacturing industry, and tobacco growers,

respectively. Their role at this meeting is to represent these industries in general and not any particular company. Dr. Heck is employed by Lorillard Tobacco Company, Dr. Lauterbach is employed by Lauterbach & Associates, LLC, and Mr. Hamm is retired.

FDA encourages all other participants to advise the committee of any financial relationships that they may have with any firms at issue.

I would like to remind everyone present in this room to please silence your cell phones if you have not already done so. If you are calling in, please keep your phone on mute. Preferably use a handset rather than speakerphone unless you are speaking, of course.

I would also like to identify the FDA press contact, Jeff Ventura. If you are here, please stand up.

[Jeff Ventura stands.]

MS. COHEN: Thank you.

Because this meeting is being held almost

totally online, it would be very helpful if people would identify themselves before you speak so that everyone knows who is speaking and also so that we can keep an accurate record of the proceedings of today.

Thank you very much.

Introduction of Committee Members

DR. SAMET: Thank you, Caryn. And I know it's a little chatter here, but some people may have had trouble hearing you. And I don't know whether that relates to your speaking a little bit softly or the way the audio is set up. But we'll let you know if there are issues as we move forward with being able to hear those of you back on the East Coast.

Let me suggest that we now do committee introductions. And what I think we can do is perhaps do the order that people are listed on the attendee list since we're not sitting around a table together. So we would be starting with Arnold, then going on to Cathy, and so on.

So if we could do a quick round of

introductions. Arnold?

MR. HAMM: Thank you, Mr. Chairman. I'm Arnold Hamm. I'm representing U.S. tobacco farmers.

DR. BACKINGER: Good afternoon. This is Cathy Backinger with the National Cancer Institute, and I'm representing the National Institutes of Health.

DR. SAMET: Greg? Gregory Connolly, are you on?

DR. CONNOLLY: This is Greg Connolly from the Harvard School of Public Health, and I'm representing the public health community.

DR. SAMET: Dan?

DR. HECK: This is Dan Heck with the Lorillard Tobacco Company, representing the tobacco industry.

DR. SAMET: Dorothy? Dorothy, are you on?

DR. HATSUKAMI: This is Dorothy Hatsukami. I'm from the University of Minnesota.

DR. SAMET: Jack?

DR. HENNINGFIELD: Good afternoon. This is Jack Henningfield. I'm with Pinney Associates and the Johns Hopkins University School of Medicine, and my specialty is addiction.

DR. SAMET: John?

DR. LAUTERBACH: John Lauterbach, Lauterbach & Associates, representing the interests of the small business tobacco manufacturers.

DR. SAMET: Karen?

MS. DELEEUW: This is Karen DeLeeuw from the Colorado Department of Public Health, and I am a government representative.

DR. SAMET: Mark? Mark?

DR. CLANTON: Can you hear me?

DR. SAMET: I think so. Give it a try.

DR. CLANTON: This is Mark Clanton, and I work for the American Cancer Society as the chief medical officer of the High Plains Division. And I'm representing public health, pediatrics, and oncology.

DR. SAMET: Melanie?

DR. WAKEFIELD: Good morning. This is Melanie Wakefield. I'm with the Cancer Council Victoria in Melbourne, Australia, and my specialty is marketing and health communication.

DR. SAMET: What time is it in Melbourne?

DR. WAKEFIELD: It's 20 past 5:00 in the morning, but the birds are tweeting already.

DR. SAMET: All right. Neal?

DR. BENOWITZ: Neal Benowitz, University of California, San Francisco, addiction, cardiovascular disease, and toxicology.

DR. SAMET: Patricia?

DR. HENDERSON: Patricia Nez Henderson, Black Hills Center for American Indian Health.

DR. SAMET: Did I miss somebody?

DR. CLARK: West Clark, director of the Center for Substance Abuse Treatment and ex officio member.

DR. SAMET: Okay.

DR. MCAFEE: Timothy McAfee, director of the Office of Smoking and Health at the Centers for Disease Control.

DR. SAMET: Good. Are you both there in person or are you on the line?

DR. CLARK: On the line.

DR. MCAFEE: Online.

DR. SAMET: Good show. All right. Good. Great. Thanks.

All right. So thank you, and we'll move then to the FDA presentation from Corinne Husten.

Corinne?

FDA Presentation

Status of TPSAC Information Requests

DR. HUSTEN: Yes. Thank you. We were just getting the slide presentation set up.

So welcome, everybody, to this next meeting of the Tobacco Products Scientific Advisory Committee, looking at the topic of menthol cigarettes. I will be presenting a little bit of data in my presentations, so I would like to say that the information in this presentation is not a formal dissemination of information by FDA and does not represent agency position or policy. It's being provided to the TPSAC just to

aid the committee in its evaluation of the issues and questions referred to the committee.

So just to refresh everyone's memory, the charge to the committee is to produce a report and recommendations on the impact of menthol cigarettes on the public health, including such use among children, African Americans, Hispanics, and other racial and ethnic minorities.

I want to just do a bit of a review of what information has been brought to the committee to date. At the previous TPSAC meetings, there was a summary presentation of the published literature on menthol in March. There were a series of industry presentations in June. There were presentations on the publicly available tobacco industry documents from the Legacy Tobacco Documents Library in October. And at all the meetings, there's been information submitted by the public.

I also wanted to give an update on the status of the information request that the committee had made to FDA. One was an analysis of

the publicly available internal tobacco industry documents. And in addition to the presentation in October, the authors' reports were also provided to the committee in October.

The literature review, the white paper summaries of the published literature, were provided in October. As part of a backgrounder of this meeting, a CD-ROM with all the articles included in the white papers was provided. There was a working table of articles in the white papers as a tool for the writing work groups as they developed their data tables.

I should just mention that what was clear to us as we were putting this data table out may not have been quite so clear in the background materials. This was designed to be a working document that the writing groups could use as they were preparing their data tables, and they could fill in, edit, add, delete, change, however they wanted.

We did receive some comments yesterday suggesting that there might be some errors in the

data table. And we haven't had a chance to review those yet, but we will. And if in fact there are factual errors, we will correct those.

The committee members will be reviewing the articles themselves and creating their own data tables for the report. And again, they can either edit these or make their own as they see fit.

There will continue to be opportunities for comments from everyone about the various articles. And we really appreciate comments, so we do want people to continue to send those in. The whole point is to have these articles well reviewed by many folks and the various interpretations put out there so the committee has robust information as they're assessing this.

So there was also a table of articles that were not included in the white papers, with the rationale about why they were not included. That was a backgrounder for this meeting. And then there have been a few articles that came in relatively recently as suggestions from the public

about other articles that should be considered. Those were listed so the committee had that information available. And so if they feel there are articles they want and they can't get them, we'll make every effort to get them for them. There were suggestions from the public, and we just wanted to make sure the committee had robust information about what was being suggested for their consideration.

The secondary analysis of existing research data that was requested, there will be a presentation at this meeting and then the authors' reports will follow as they're completed. The presentation today will be the preliminary findings, and then the authors will submit their individual papers, and those will come to the committee.

There was a request for menthol cigarette sales data. There'll be a presentation at this meeting about the Nielsen data findings. And then there was a request for some modeling of menthol cigarette use, especially around initiation and

cessation, and that model is under development.

As far as the industry documents, FDA will complete a review and analysis of all industry documents that were submitted, but this review and analysis may not be entirely complete before the TPSAC report is due. We are working diligently to get as much information to the committee as soon as we can. We have analyzed responses to four questions by FDA staff, and we'll be getting those to the committee shortly.

The questions that we've analyzed so far are questions 13 to 16. As you recall, we had been requested to get information from the tobacco industry on 16 topics. We sent a letter to 108 manufacturers. The responses to questions 13 to 16 were voluntary, not mandatory. The responses were narrative in nature, not document submissions. And we have reviewed the information submitted on those questions, and we are working to determine how to make this confidential information available to the committee.

We also obtained some data from the FTC.

And one piece of data from that can be made public, and that will be presented at this meeting. But the other data that we received is confidential and cannot be shared in a public forum.

As far as the writing work groups, the work groups are starting to meet. We have made a small change in the process for the writing work groups. We had originally said that the DFO would be present at all phone calls and meetings; but in an effort to expedite the process, we have now decided the DFO has to know about every meeting, the meetings times and the attendees, and has to be copied on all correspondence and exchanges of drafts, but does not necessarily have to be at every single meeting of the writing work groups.

So for the one piece of data that I have to show today are the data from the FTC. This is data about the number of menthol varieties for what are characterized as menthol and non-menthol brands. And by "varieties," that's basically the sub-brands.

What these data show -- I should just say a caveat first, that the FTC data is only data from the largest manufacturers, so it's not all manufacturers. Menthol brands are basically the brands that sell only menthol cigarettes or have very minimal non-menthol varieties, and then the non-menthol brands are all the other brands.

I would encourage everybody not to focus on individual data points because there can be variation from year to year, and because of the timing of the collection, things can look a little strange one year compared to the other, but to look at the overall pattern that you see here. And basically, it's showing that the menthol brands have been pretty stable in terms of the number of varieties, but that there has been an increase since 1992 in the number of varieties or sub-brands for the non-menthol brands, those that are not essentially totally or nearly totally menthol brands.

Our next steps, at the next meeting, we again will present updates on the information

that's been requested by the TPSAC. We are asking at the next meeting, which will be in the first quarter of next year, that each work group present a summary of the scientific evidence relevant to each of those chapters so that the evidence that they're using as they're developing their conclusions and recommendations is presented in an open setting and can be discussed.

Any clarifying questions?

DR. SAMET: Thank you, Corinne.

Does everybody remember how to raise your hand if you want to ask a question? I assume, if I've got this right, that you click. So let's see; Karen has her hand up. So Karen, and I see Greg also.

MS. DELEEUW: Yes. This is Karen DeLeeuw. Recently, this supplemental addition to the Addiction Journal and the role of mentholated cigarettes in smoking behavior, I was just wondering how that might or might not be made available to the members of the committee.

DR. HUSTEN: Yes. Thank you. Our plan

was to make that available to the committee. I had actually thought we might be sending the link out before this meeting, but that may not have happened. But you will be getting it very shortly.

MS. DELEEUW: Thank you.

DR. SAMET: Greg?

DR. CONNOLLY: Yes. As a follow-up to that, I believe there's a supplement coming out, tobacco control, possibly. I don't know. But if that does come out prior to the meeting, how will that be handled?

DR. HUSTEN: Well, as we had --

DR. CONNOLLY: This is on the internal documents presented at the last meeting.

DR. HUSTEN: As we had mentioned in an earlier meeting, as we become aware of relevant articles, whether we find them or someone tells us that they're out there, we will make every effort to make them available to the committee. So if you can let us know when it's available, we'll get it out to the committee.

DR. CONNOLLY: Then a second question, at the last meeting, we did talk about experts in the area of bootlegging. One was Luk Joossens. And that is part one of our mandate, where I think we clearly haven't addressed it. It could be a weakness in the mandate.

Will there be any attempt to address the issue of bootlegging with an expert? I think we mentioned one expert.

DR. HUSTEN: We are working to try to secure a speaker at an upcoming meeting who can speak about the issue of contraband.

DR. CONNOLLY: Then two other questions and I'll end.

Under Section 903, your mandates, registry reporting -- I believe it's 1, 2, and 4 -- it may indirectly affect the report we're writing. What you're telling me now is that we have been voluntarily asking questions that were listed in the Federal Register, but there is a slowness in production of those documents.

Do you have any plan on how the group

will get information from the industry that is mandated so that we can make a decision based on the widest available --

DR. HUSTEN: Yes. Let me clarify. Questions 1 through 10 had mandatory responses. Those are the ones that we are working to get analyzed. We'll get you as much of it as we can within that time frame that we have. What I was talking about, the voluntary submissions, are questions 11 through 16.

DR. CONNOLLY: Then tied to that is, it is my understanding when the Minnesota court settled with the tobacco industry on their case, that privileged documents were given to the FDA but not made available in the depository.

Has the FDA made any attempt to look at those privileged documents or do they still have them in their possession?

DR. HUSTEN: I will have to check on that.

DR. CONNOLLY: Then the final question is, we are focusing very heavily on data

accumulation so that we have the best science possible to answer very difficult questions. The report also calls for recommendations, and it is not necessarily a recommendation yes/no. I think we're facing some very difficult issues here which could have a number of recommendations that emerge from the group.

Are we going to have time as a group, given the deadlines that we have, to devote to a session on recommendations?

DR. HUSTEN: We have been trying --

DR. SAMET: Corinne, you might want to answer that. But, Greg, we are certainly, as we discussed, developing the documents, looking at how we'll have an opportunity in public session to look at all the material that's been written and think about the recommendations.

Corinne, do you want to elaborate?

DR. HUSTEN: No. That's exactly right. I mean, we are trying to develop and have developed a proposed timeline that will certainly allow for public discussion of what the committee

feels are the appropriate recommendations.

DR. CONNOLLY: Thank you.

DR. SAMET: John? John Lauterbach?

[No response.]

DR. SAMET: Dan?

DR. HECK: Yes. Dr. Husten, I thank you for that clarification -- excuse me. Am I still on?

DR. SAMET: Yes, you are.

DR. HUSTEN: Yes.

DR. HECK: Thank you for that clarification that the information summaries distributed are the working documents and subject to revision and correction. I did submit some corrections that had come to my mind, and indeed today I received another dozen or so.

The concern I have, though, is that some of the corrections that I had pointed out had indeed been made on the record before in previous TPSAC proceedings, and I would like to have some assurance that those corrections are being considered and taken seriously and acted upon

where appropriate.

DR. HUSTEN: Yes. They are all being taken seriously, and we are going to very carefully review everything that's been submitted. Some of this may have been different people working on things at different times and some time pressures. So we are definitely going to look at it, and any corrections that need to be made will be made.

DR. SAMET: I will say, just again, that this is a working table that is intended to help guide the writing groups. But I think as the writing groups begin to dig deeply into their task, I'm sure they will necessarily review the original studies in their findings.

Let's see. We'd lost John Lauterbach before.

John, are you on?

DR. LAUTERBACH: I think I'm on.

DR. SAMET: You are. You are definitely on. Go ahead.

DR. LAUTERBACH: The question was, back

on the comment from last meeting by Dr. Husten on the responses from the tobacco companies or -- that discussion, do we have any more information, particularly realizing that many of the 108 companies are the smaller companies that wouldn't have any of these documents or information that Dr. Husten had mentioned?

DR. HUSTEN: I'm not totally sure I'm understanding the question. But certainly we have received responses saying we don't have those data or we don't know the answer to that question.

DR. SAMET: Let's see. Greg, do you have further clarifying questions?

DR. CONNOLLY: Just one, based on what Corinne just stated.

Corinne, it sounds like it's a process where FDA is both reviewing, revising, updating, and correcting, while at the same time the committee is working. So can we expect further CDs with information, with templates, so that there's continuity in this process where we're learning as you're learning?

DR. HUSTEN: Well, we expect, other than if we either find on our own reviews or if people let us know about other published articles, that we will just be sending you those as we become aware of them. We do not intend to be going back and revising white papers or anything like that. Anything that's coming forward from this point on will just be sent to the committee for them to review and include.

As far as other products, again, the committee is going to be reviewing the articles themselves, and the materials are really designed to be there as a tool, as a place to go to find which articles are out there, which ones may be out there that weren't included in the white papers, to just give people as much information as possible so that they can critically review the literature and write the chapters.

So we don't plan to be doing a lot more synthesis of new information. We are going to review the comments that came back about the data table. We are going to try to do that fairly

expeditiously because we know the writing groups are starting to work, and we want to make sure that if there are any errors in there, that those are corrected. But the information analysis piece of this is really shifting to the committee members at this point to be doing their own review and critical analysis of the data.

DR. CONNOLLY: My only comment would be that, Jon, you should feel comfortable with both the structure of the white paper and the tools for the data presentation so the committee then can function in a coherent way between the different reports.

DR. SAMET: Sure. Sure.

DR. CONNOLLY: The more direction you could provide I think he more helpful that would be.

DR. SAMET: Yes. And remember, we also have Denise as the editor to provide, from the contract oversight deal.

DR. CONNOLLY: Thank you.

DR. SAMET: Dan, did you have another

clarifying question?

DR. HECK: Yes, just a little minor follow-up. I think some of my distress came from the fact that the table received was labeled "Final Version," and that led me to believe this was final, rather than work in progress. So maybe a minor revision to that title would --

DR. SAMET: Yes. The title, yes, we've discussed that, actually.

DR. HUSTEN: Yes. The file was saved as that. I actually don't think that was the title of the table, but the file was saved as like that was the final to be submitted up into the Internet and sent out. But, yes, like I said, what was clear to us was not as clear in the materials. And so that's why I wanted to clarify here that this is designed to be a working document. If the committee finds it useful, they can use it. If they don't find it useful, they don't have to use it.

It was purely -- we had heard at the last meeting that the committee was feeling some

pressure, that there was a lot of work ahead of them, and it was just an attempt to give them some information that they could use or not use that might help them.

Update on Menthol Report Subcommittee

DR. SAMET: Thanks. And I think we also understand that when you review large numbers of articles on a fairly rapid basis, you sometimes have to make judgments about exactly what is there, subject to interpretation and sometimes subject to mistakes. And I think the input is helpful in making sure that these are as accurate as possible even though they are working documents.

I think we should move on. The next item on the agenda is me giving you a very quick update, perhaps refresher, on what we are doing in developing the menthol report. And I don't think we need to spend too long on this, but this will really just run back over sort of where we are.

First, we have this framework of a model to guide some of our thinking, and, again,

recognizing that there may be changes to this as we move through. We have identified the chapters and their authors, and the chapter groups are beginning to hold meetings. There have been a few additions you'll note in blue. Melanie added to chapter 5 and myself added to chapter 7.

A number of these groups, I think, have either met -- the chapter 1-2 group has, and I think others are getting underway -- and obviously we have a tight schedule leading up to our January 10th-11th meeting. So this is just a reminder, and then those additions to the authors.

You'll recall that there are specific questions. There are two groups of questions, those related to individual smokers and those to smoking at the population level. There's not a specific mapping per se of these questions onto the chapters; that is to say there's not a one-to-one correspondence necessarily between questions and chapters. What that means is as we come back and start to go back and forth a little bit -- but as we come back to our committee conclusions and

recommendations and look at the answers to these questions, there'll be interactions across the whole group.

Of course, everybody's involved in multiple chapters and with some semblance of theme, so that I think the move from our reviews of the evidence around topics to using and make those reviews as the basis for developing the answers to the questions should come together. Obviously, we'll need interactions, the kinds of interactions that we will need to make sure we have time for in our January meeting.

So these are the questions, again, remember just the two groups of questions related to individual smokers and then to the population-level impact.

Then moving on again, we've talked about the general approach that we're going to use to the menthol report. Transparency in our processes will be important, that we're going to carry out systematic reviews, reviews that will be defined by the search criteria in each group, developed as

appropriate. We've developed some ideas about how to synthesize evidence and to assess the strengths of the evidence, again, work we've done in our prior meetings.

So as the general approach, describing the sources of evidence -- and, again, some of those are in the searchable peer-reviewed literature, and some of those lie in documents and the other materials that are being brought forward to us; for example, the kinds of analyses we'll hear about today or that have been presented in past meetings -- and evaluation of the evidence, what is there, the assessment of the strengths and weaknesses, and classification of the strengths of evidence.

Then, towards our overall task of evaluating impact, this is where modeling approaches will be helpful. The extent to which models are going to be available I think is still something we'll have to wait and see, but we're hoping that we'll have tools that will help us to make some judgments that may be perhaps not

rigorously quantitative, but semi-qualitative or qualitative, at least allowing success, directions of impact.

Then, just a reminder, we talked about the evidence classification scheme at our last meeting. We talked about the idea of equipoise or balance, and had come up with this four-level scheme that is shown here that would be used by the groups. And I think that's my last slide.

So this was just a sort of reminder of what we have in motion at this point. So let me ask if there are any comments or additions.

Corinne, do you want to add anything?

DR. HUSTEN: No.

DR. SAMET: Let's see. There are a couple of hands up here. Melanie?

DR. WAKEFIELD: Yes. Thanks, Jon. Just in relation to the first slide, the model that you have there, I just wanted to -- at the moment, you have marketing as an influence in looking at adolescents, whether or not they experiment with smoking.

DR. SAMET: Right.

DR. WAKEFIELD: I think it's important to capture the fact that marketing can influence whether or not experimentation progresses, and marketing can also influence whether or not people decide to have a go at trying to quit smoking and may actually succeed or not. So there's a couple of other points --

DR. SAMET: Right. For sure. So let me make a comment. I certainly agree, so we should make suggested changes. But any other comments or changes on this figure would be welcomed. So for sure we will make that addition.

DR. WAKEFIELD: Thank you.

Greg?

DR. CONNOLLY: I've got to hop back just to one quick point on the RTI work on the menthol data. And let me get to my question.

Corinne, I think it'd be helpful if we do -- if what the prices were, if that was adjusted for price, and Nielsen does provide price. Then, number two, the number of new brands

that are entered into the market for menthol versus non-menthol, that would be very helpful for understanding. And then you could get as a separate data source -- RTI could buy it -- the level of menthol expenditures in the advertising versus non-advertising. I can give you the data source. Those three elements could help elucidate this chart a lot better and control for other risk factors.

I just want to go -- I think you did a good job, Jon. And I just want to go back just on history, without creating any problems here, that as a group, we came together in March and we set five areas of work. One is characterization of menthol, menthol cigarettes. Two is clinical effects of menthol, which could be individual effects, I think. Three was biomarkers, which looked at toxicity. Four is marketing data. And five is what the law was doing, what's population effects. So that's what we initially did.

At our last meeting, we came up with the menthol report preliminary chapter outline. We

could exclude 1, 2, and 8. One was introduction, 2 was evidence, 3 was conclusion and recommendations. Then 3 through 7 include physiological effects; patterns of smoking is 4; initiation, cessation, which was 5, which I kind of think it collapsed. Risk was toxicology. Public health impact was going back to population effects.

Now we have before us -- it looks like a somewhat different approach than we began with in March and we agreed to at the last meeting. And I'm just arguing that we should be learning collectively as a group of people approach and historical respect for what we're doing. And I'm not criticizing.

DR. SAMET: But, Greg, actually, there's no change here from where we were at our last meeting.

DR. CONNOLLY: Okay. So we agree. Okay. All right.

DR. SAMET: There's absolutely no change here at all from our last meeting.

DR. CONNOLLY: I'm just saying we respect our history.

I think that one thing I would say is the law seems to provide a balance. And we as a group, early on, before we get too deep in this process, have to understand that balance. The law has very specific guidelines for modified risk tobacco products that focus almost exclusively on toxicology.

On the menthol, it talks about public health impact. So rather than on individual effects or on toxicology effects, it seems to be speaking to population effects of initiation, continued use, and effects on the population as a whole.

I think as a group, we have to make a decision -- and it's come up before just as hearsay or side statements -- is this report going to be more focused on population effects of initiation and cessation or is it going to delve into the area of toxicology?

I could just share my own opinion, and

that is, cigarettes are very lethal products, and in trying to differentiate one constituent from 5,000 in harm is a really, really difficult task. And I would feel more comfortable in satisfying what the Congress has mandated the group and almost end the model -- I think I said this to you, Jon -- where we don't consider death a disease.

The other final point I want to make, Jon, is that the data we've been presented, at least for the adolescent Caucasian initiation smokers, would indicate they do not stay with menthol, that they're switching to non-mentholated cigarettes as they age.

Now, we have to look at that data carefully. So I think the model needs a little bit of consideration of the fact that the adolescent Caucasian smoker appears to be using menthol at the start and then switching to a non-mentholated brand.

At the beginning of the model, I think you could put product design and all that.

DR. SAMET: Right. So let me suggest, though, I think there could be multiple models or some aspect of models that move in greater depth. I think we have to wait and see as a committee sort of what kinds of expertise we will have available to us.

I think, Greg, in answer to your comments, I think it's been referenced in chapter 6, and chapter 6 is a necessary part of our report, and in part because there is some literature that is relevant. And certainly there are a number of indicators of public health impact. Obviously, mortality from smoking-caused disease is one.

So I think we will, as we come back to that discussion, be looking at what the multiple indicators of public health impact we might consider are.

DR. CONNOLLY: Okay.

DR. SAMET: All right. So I'm going to move on, Greg.

DR. CONNOLLY: Jon, let me just say I

agree with you. I think we have to think carefully on how we create a construct for leading from population effect to the disease burden; that it's not going to be one that is traditionally accepted or put forth in surgeon generals' reports.

DR. SAMET: Okay. Karen? Let's see. Karen, did you have your hand up?

MS. DELEEUW: Yes. I'm sorry. This is Karen DeLeeuw from Colorado. Getting back to the model, I was wondering if we could do some representation of switching behavior between -- maybe some line or something between menthol and non-menthol just to remind us that there are some dynamics there and patterns there that deserve attention.

DR. SAMET: So I guess -- let me ask. Maybe the best way to make these changes is to send them through Caryn Cohen, and that can be incorporated.

MS. DELEEUW: Okay.

DR. SAMET: Then we have the suggestions

from Melanie.

Jack?

DR. HENNINGFIELD: Can you hear me?

DR. SAMET: Yes.

DR. HENNINGFIELD: Good. I want to add to Melanie's comment about the influence and importance of marketing in addiction. And I think, basically, the model works well. But whether we need a footnote or something, we need something to make it clear that addiction is not just a box where pharmacology interacts with the organism, except in laboratory settings with animals. Addiction occurs in a social and very active environment in which marketing factors play an important role.

So in the real world, the development of addiction, the severity of addiction, the persistence of addiction, and the adverse consequences can all be modulated by efforts beyond pharmacology, and in particular, marketing factors. And this includes price, availability, image, perception of the risk, perception of

benefit, and so forth. And this is all true and equally true of cocaine, of marijuana, of alcohol. It's been highlighted by the surge in prescription drug abuse.

So I'm not sure that we need to radically modify the figure, but we do have to make it clear that addiction is not just a box on a figure, but it's an area that is influenced by all these factors. And menthol is something that can interact in many ways because menthol is not just a substance, but it's a marketed factor.

So, again, I'm not sure that we have to modify the figure or model radically, but at least recognize those interactions.

DR. SAMET: So I will repeat the famous quote from the statistician, George Box, who said, "All models are wrong, but some are useful." I think that the main point here is that, obviously, a huge amount is oversimplified.

Here, if we began to draw out the best representation of how we think the real world works, we'd have lines all over the place. I

think what we need to do, and in part this was some of my purpose in oversimplifying, was to think about those steps where we might find some literature that we'd allow to make some sort of quantitative assessment so that we could build a model.

So recognize simplification. I think in the text that goes with this, we really need to acknowledge that this or one or more figures that go with it deal exactly with what you said, Jack. And in fact, we might have some models that speak to the complexities around addiction, in fact, highly multi-variant with many factors and interactions among the factors. So I think the point is well taken, and I think this is something the writing groups will need to deal with.

Let's see. So I'm still dealing with clarifying questions. Greg, a clarifying question?

DR. CONNOLLY: Yes. I just had a brief portion, what Jack said. I think we've got to get back to you with the changes in the model. It's

an excellent model. I think you've done a great job in trying to make it simple so that people can understand it.

At the last meeting, I think we learned that marketing parents in pairs were really different categories. And I think I just want to get on record my interpretation of what I heard.

Marketing includes what the industry is doing relative to pricing behavior, advertising, and actually, the design of the product itself in the menthol. I think they're all related in terms of its effect on initiation and continued use.

Parents, peers, and I think you could also include in that, Jon, social, ethnic, environmental factors, that are very true for menthol but that are separate and that we have to look at and consider in any report. If we don't, I think we are underestimating the influence of the history of menthol use within the African American community.

Now, when we get to 2, menthol properties, the term "taste," there was a lot of

confusion at the second meeting with the industry, what the definition of taste was. I hope the industry could help us define taste better.

But if you look at certain countries, there's a very low level of -- in my opinion -- I've seen data where the brand family is marketed heavily for awareness. But the sub-brand family -- let's say menthol is in a sub-brand within a larger family -- the traditional marketing doesn't seem to play as much of a role as the actual action of the menthol, the flavor, the taste, the color of the package. And what I was told what we've --

DR. SAMET: Greg, I think you've got your point over.

DR. CONNOLLY: Okay. But just let me finish. What I was told is that the industry stopped marketing menthol in a traditional media sense but hadn't changed the properties. That has to be taken into very careful consideration by the subcommittee. These are very subtle points, but I think they deem consideration by the subcommittee.

DR. SAMET: Perhaps each writing group, as they approach their particular chapter, may want to draw out some of the expanded representation of their particular area.

Melanie?

DR. WAKEFIELD: Thanks, Jon. I had just a couple of suggestions about some of the questions that had been posed.

First of all, related to individual smokers, if we could go to those slides, particularly question 5, which was, "Are smokers of menthol cigarettes most likely to quit successfully than smokers of non-menthol cigarettes?", I think it's important to include the possibility here that smokers of menthol cigarettes might postpone even trying to quit more than smokers of non-menthol cigarettes.

So it's not just that there might be a differential quit rate; it may be that there might be a differential trying to quit rate, which is perhaps just a small point that I think is worth adding just for the sake of being inclusive.

Then secondly, there are questions on smoking at the population level. The second one here, which was, "Does tobacco company marketing of menthol cigarettes increase the prevalence beyond anticipated prevalence if such cigarettes were not available?" I suppose most of these questions are really pointing to behavioral kind of evidence in the population in terms of smoking behavior. But I do wonder about the role of misperceptions about harm and false beliefs about -- or expectations about what the benefits of --

DR. SAMET: Wouldn't that be mediating, though, in the end?

DR. WAKEFIELD: They are. They are, absolutely.

DR. SAMET: Yes. I think this is the attempt to get at this question of impact. And I actually think the question is okay. I think what you're exploring are some of the --

DR. WAKEFIELD: The pathways.

DR. SAMET: Pathways. I don't think, in

terms of some the questions that we need to answer in developing the recommendations from our report, yes, the mediation is of interesting importance. But I don't think we necessarily, as a committee, need to answer the question mediating and what might mediating pathways be, but address the question as it's stated here.

DR. WAKEFIELD: But that doesn't preclude us from (unclear).

DR. SAMET: No, no. Not by any means, no.

DR. WAKEFIELD: Okay. Thanks.

DR. SAMET: Yes. No one has their hand up, and I'm going to take advantage of this moment to suggest we move forward in our agenda, to hear the reports from RTI, the first from James Hersey on the secondary analysis of the effect of smoking menthol cigarettes.

Let's see. So I guess the presentation is up and we're ready to move on. So we have a half hour for this. I think we were hoping to have roughly 10 minutes for questions. So if

you're ready, please go ahead.

DR. CONNOLLY: This is Greg. Can I just ask a clarifying question?

DR. SAMET: Greg, no. We've got to move on. No. I'm sorry. Not at this point.

Let's go ahead with the presentation. James?

Secondary Analysis of the Effects of Smoking Menthol Cigarettes

DR. HERSEY: Delighted to be here. Jim Hersey from RTI. And what we did was, on support of FDA, conduct - or solicit some secondary analyses of existing data sets that might support the committee in its decision-making, which is a nice way to say, basically, we're using information in the following presentation; it's not a formal dissemination of policy of FDA.

We have looked at information on topics of interest related to initiation of cigarette smoking, dependence, cessation, and the health effects of smoking. We really gave priority if we could find cohort studies or studies which could

look at the effect of menthol, controlling for race, ethnicity, or smoking intensity.

We said most did solicitations, lots of great help from the American Public Health 01:16:09Association, ATPR, CDC, TANRIG, SRNT, in getting applications in. These were independently reviewed by a team at RTI and Roswell Park, and also by FDA independently. Of course, we didn't review our own applications.

We looked at these in terms of scientific merit and feasibility, and ended up awarding 11 grants in September. So people have had about six weeks to conduct these analyses. These are kind of interim analyses, in that findings have not yet undergone peer review. So the committee needs to be alert to that.

Of the 11 awards, one looked at initiation of smoking, five looked at the issue of tobacco dependence, three at cessation, two at health effects. And I'll go through them quickly to give you a sense of what you'll be receiving in the next few weeks as you look through this set.

In terms of initiation of smoking, my colleague, Jim Nonnemaker, with support from a data set where Donna Vallone had helped us and Jane Allen from the Legacy Foundation, really looked at a cohort study, the last wave, where we had three waves of data over three years. And we were looking at people who started.

The first wave was a menthol cigarette; were those people more likely, in terms of progression, to move towards daily smoking or toward established smoking? And we analyzed this using nontypical regression methods.

Interesting findings, to probably read it a little more closely; but youth who started out their first cigarettes at wave 1 -- they were smoking menthol but they weren't yet established smokers -- they're more likely to be daily smokers by wave 3. They're also more likely to show indicators of dependence. We had a dependence scale that Jim Nonnemaker had developed. And we have some data as well there on switching; but some suggestion that early smoking of menthol

cigarettes may move you towards a higher progression, both towards daily smoking or also towards established smoking.

In the area of tobacco dependence, Josh Muscat looked at the modifying effect of tobacco dependence, dependence on tobacco risk. He's using a big data set as well as a small one in New York, and he's really looking at the regression model with blood cotinine or lung cancer risk. And, again, he's finding, as we've often seen before, time to first cigarette in the morning clearly related to increased risk of lung cancer and smoking harm. But that doesn't appear to be differentially related for menthol versus non-menthol cigarettes.

The second study we did was one that I led, working with some help from Donna Vallone, again with a Legacy data set, where we'd actually collected among adolescents, fairly big, 5,000 -- where we collected saliva cotinine measures. And so we looked at effects of smoking menthol both on cotinine levels and also on nicotine dependence.

We ended up looking at about 500 -- a little over -- just under 600 kids.

Menthol cigarettes by themselves didn't have a direct impact on cotinine levels. However, there did seem to be an interesting interaction, where, among new smokers, people who smoke for less than a year, new smokers who were smoking more cigarettes, if those cigarettes were menthol, were more likely to have higher cotinine levels than smokers of non-menthol cigarettes.

We also looked at the issue of menthol and dependence. And again, while there's nothing which worked for the entire sample, there may be an interesting finding of menthol and nicotine dependence among the newer smokers.

My colleague, Andy Hyland, at Roswell Park, along with Cheryl Rivard, did a couple studies really looking at dependence and cessation. The first was an analysis with the COMMIT study, which is kind of a cohort from '88 to 2001, running regressions. He was looking at switching and indicators of dependence. There's

not a whole lot of switching. And there didn't seem, in the COMMIT study, to be a relationship between smoking menthol cigarettes versus non-menthol cigarettes on nicotine dependence or switching or cessation success.

More recently, the team analyzed data from the International Tobacco Control study, with a U.S. sample, and so that's got about 7,000 people. The sample starts from 2002 to 2008. They're using, again, multivariant analysis. First they looked at switching, which is a little more common from -- whites are more likely to switch to non-menthols, and African Americans are more likely to switch to menthols, but there's not a whole lot of switching altogether.

However, after you're doing your typical statistical control, your menthol smokers are reporting fewer minutes to their first cigarette. And so that's kind of an interesting finding about nicotine dependency.

Lorraine Reitzel at the University of

Texas analyzed, actually, three studies, which deal both with dependence and cessation. These are three samples of smokers going through a set of cessation trials, and she was analyzing baseline data about tobacco dependence. So I'll quickly summarize each of the three studies.

In BREAK FREE, which is about 400 respondents, again black smokers, menthol cigarette use was associated with high taste sensation processes in Wisconsin major tobacco dependence. But that wasn't related to continuous abstinence, subsequently.

In a second project, which is Project CARE, again this was a sample where it was about a third African American, a third Latino, a third white. The menthol cigarette was not related to dependence or continuous abstinence. But, again, there was some indicator of greater dependence on mentholation, Behavioral Choice Mentholation scale on the Latin population.

Finally, she looked at Project MOM, which is a sample of women who were pregnant or recently

pregnant, trying to stop them from re-smoking again. And menthol cigarettes were associated with smoking per day and higher rates of smoking relapse.

To continue this kind of issue of dependence and cessation, Christine Delnovo of UMDNJ looked at the relationship between menthol smoking, using data from the 2003 tobacco use special supplement. Again, she's using multiple regression kinds of analyses. And she's finding that among current and former smokers who have quit within the past five years, those who smoked menthol were significantly less likely to have quit smoking than those who smoked non-menthol cigarettes, and that this relationship was actually stronger among African Americans and among Puerto Ricans.

Jennifer Unger of the University of Southern California looked at menthol with a small sample of African American smokers. What was unique about her study is that one of the things she did was really use mall intercepts to really

get a bigger sample, a bit more inclusive kind of sample than you would from a typical telephone survey.

She also looked at not only a menthol/non-menthol, but against people who reported smoking both kinds of cigarettes. And again, she was not finding huge differences between menthol and non-menthol or even the mixed group.

Andrea King at the University of Chicago had an interesting study which was looking at a clinical trial of cessation. She looked at effects of cessation between menthol smokers and non-menthol smokers. And so in this trial -- this is an African American sample, or half of it African American, other half Caucasian. But in this sample, she was doing -- the control group received traditional counseling and the nicotine patch. The experimental group received this patch plus an opioid antagonist or pharmacological therapy.

What she was finding was that among

whites, the white sample, menthol really didn't seem to have much effect on cessation rates. In people, African Americans, who went through traditional kinds of cessation programs, a patch plus counseling, the menthol smokers had lower quit rates; but among the African Americans, if they were in the experimental group with the opioid antagonist plus the patch and counseling, the quit rates -- among that group, the success in quitting was equally as great among menthol and non-menthol smokers.

Finally, we had a couple sdy7s looked at health effects. Steve Stellman and Alfred Neugut of Columbia looked at, really, the risk of cancers, and a variety of kind of oral cancers, again running logistic regression with a big hospital sample. And, again, they're finding that the risks of cancers in menthol smokers versus non-menthol smokers are really not significantly different for lung cancer or cancer of the esophagus, which is new in the study, cancer of the oral cavity, larynx cancer, bladder cancer.

So, yes, not significant. My own words is that yet again, as Gary Giovino would say, menthol cigarettes are just as deadly as non-menthol cigarettes.

Finally, a study from Andy Hyland which was looking at COPD and lung cancer in, again, a big case-controlled study provided by Roswell's data bank using multiple-variable regressions. And again, they looked at -- the percentages of men who smoked menthol didn't differ differently from case controls. Percentages of women who smoked menthol were actually somewhat lower among cancer patients. But really, the bottom line is there really weren't huge effects for menthol in this sample.

So in terms of next steps, we're going to be submitting these reports to TPSAC as soon as FDA has a chance to look at them, which means getting our production department. And it's going to be authors' decisions whether or not to submit the papers to peer review. But I do think that, in total, these studies help fill up some of the

gaps that were addressed, identified at the first meeting of this committee, and I hope that they're helpful in your deliberations.

Thank you.

DR. SAMET: Thank you. And before we actually turn for clarifying questions, I know we were all struggling to hear. There seem to be two problems, low volume, and then there's a fair amount of background static right now. And I don't know whether somebody's on a cell phone who might mute, if that would help, or something.

Tom or Karen, are you working on this? Is something working on this?

MR. GRAHAM: We are, Dr. Samet. We're trying to get somebody to fix it right now.

DR. SAMET: Thank you. The static seems to be more recent, but the volume problem I think had been somewhat pervasive throughout the call. So thanks.

So thank you for your presentation, Jim. It looks like a lot of interesting projects in the works.

Let me go ahead and ask for clarifying questions. And I think at the end, maybe, after those questions, it would be helpful if between you representing RTI and -- I guess, Corinne, we had a pretty firm understanding of what the timetable might be for the submission of the reports through FDA to TPSAC, when we would have these in our hands.

Jack?

DR. HENNINGFIELD: Thank you. A very helpful summary. And I just wonder if you would agree with this characterization or where you would disagree.

As I listened, my conclusion is that these data suggest that menthol is associated with several different measures of increased risk of dependence, including level of smoking, as well as measures that are not conventionally used to assess dependence, and also delays in cessation.

The effects are not always strong. They're not completely consistent. But it appears that if there is an effect of menthol, it's more

likely to be in the direction of the increased dependence and decreased cessation, and not the other way around.

Is that a fair characterization?

DR. HERSEY: I think broadly that is. Again, cessation results tend to be a little more split, but that's what you'll find in the literature. I think it's wise for the committee to read these papers, looking for the effects of menthol in terms of nicotine dependence and in terms of uptake in case they should happen to accelerate that, and particularly to be attentive to the effects of menthol cigarettes among newer smokers because I think that may be a particularly vulnerable group to the effects of menthol.

DR. HENNINGFIELD: That's really helpful, and I'll be interested in comments or views, at any point, of other addiction experts on this panel, including Dorothy Hatsukami and Westley Clark and others, because I think the challenge to the committee is, when we have data that include apples and oranges and grapes and other things,

how we view them.

DR. SAMET: Greg?

DR. CONNOLLY: I think I'm going back to Jack's question. You're presenting both data on youth use as well as adult use, and I was just trying to differentiate between the different reports. It seemed the first presentation was from Legacy on youth use. You later went to the TUPS survey on youth use, and it seemed like you made inferences that there'd be a role for initiation.

You referenced the COMMIT study, which to my understanding only looked at heavy smokers. And I wonder if that would confound the findings of the COMMIT study if these are very heavy smokers because the COMMIT study, overall, I don't think found an effect of all the interventions on quitting among the COMMIT study.

You referenced the ITC study, and I know concerns have been raised about the sample size on ITC, particularly when we get down to sampling youth and can we determine a factor in youth.

I didn't see a breakout in terms of heavy versus light smokers or occasional versus daily smokers in some of the analyses. And so I have kind of a difficulty in looking at apples and oranges and interpreting the data.

I would say that your finding on health effect seems very reasonable. The finding on quitting, I think there are some confounders there. I even question the validity of using mall intercept surveys since they're not random; it's only reporting on who comes into malls, and there could be a lot of bias built in there.

On initiation, I think you seem to be pointing towards the role of tobacco use with menthol as initiating. I was curious: In any of the studies, did they break out brands? Did they look at Newport versus Kool on initiation?

DR. HERSEY: No. The answer to that question is that usually our sample sizes didn't permit that level of kind of analysis. Most of the studies we had in the set really were among adults. The Legacy had funded the two youth

studies, where we begin to see some initiation effects. We can take a look and see whether a difference in heavy or lighter smokers; that I'll have to reread these to try to get back to you.

But I think you're right. These are not one cohesive set of studies. Rather, they were designed to identify needed gaps, and you're going to probably need to break them as a committee into these which deal with young people, these which deal with cessation.

DR. SAMET: This is Jonathan Samet. Let me just perhaps ask a question that will clarify, I think, what Greg asked.

If I understand correctly, you had a process in which you solicited analyses of relevant data sets from the broad community.

DR. HERSEY: Yes.

DR. SAMET: And this is what you received. You have not attempted to, let's say, necessarily standardize approaches, analyses, variables, in any way across this group of, I guess, 11 investigative teams.

Is that correct?

DR. HERSEY: That's a correct statement.

DR. SAMET: Have they met together and discussed, or has this been all individual work?

DR. HERSEY: Our time frame to support your committee didn't allow that kind of time to do that. That's a good suggestion.

DR. SAMET: Right. I guess a sort of related question. I think we all will have to work with the heterogeneity of the data sets. I mean, some of these data sets go back almost 30 years, the old American Health Foundation case control study, for example.

But in terms of the process that is envisioned here, a report will be developed by each group. If TPSAC finds issues that might be explored informatively for our purposes in these data sets, is there a mechanism for going back to the investigators and saying, well, what about providing this one or more additional analyses?

DR. HERSEY: I would defer to FDA about the answer to that. But my experience, having

dealt with the investigators, is that they're very cooperative and very supportive of this effort, and would be interested in doing stuff like that.

DR. SAMET: Then I think the question of timetable?

DR. HERSEY: We'll get these reports to you soon, maybe by Thanksgiving.

DR. SAMET: Okay. All right. Dan?

DR. HECK: Well, I just might say this. I'm at a considerable disadvantage here, having not had any exposure to this endeavor here, this project, and any ability to review this material in advance. But I do suspect that there will be some considerable comment that could be made on these studies, and I'll look forward to the TPSAC sharing this material with the industry representatives when that's possible.

DR. SAMET: I will say that I think we've all just seen this at the very same moment. I think the burden on us who receive these reports will be to carefully evaluate them because they will not be coming through the usual peer-reviewed

mechanism. And I think we'll have to make certain that we look closely at what they have found and the methods used.

Cathy?

DR. BACKINGER: Yes. James, I'm just wondering whether -- or I think it would be useful for when the various authors write up their reports for FDA to, as much as possible, have a standardized format; and maybe, more importantly, making clear what -- as opposed to submitting for peer review, when you have less words, but making sure that we understand, or the writing group especially understands, all the methodology within each of the studies.

So, for example, I'm looking Lorraine Reitzel's study, and I say, okay, 399 black smokers in project BREAK FREE. But where are the black smokers; what age were they; when were the data collected, those kinds of standard methodology delineations.

DR. HERSEY: I believe you'll see that in most of the papers. I can confirm that.

DR. BACKINGER: Okay. Thank you.

DR. SAMET: Seeing no other hands up, I'm going to suggest we move to the second RTI presentation by Brett Loomis.

Trends in Menthol Cigarette Sales, Price and Promotion in the United States

DR. LOOMIS: Thank you very much. I hope everybody can hear me.

DR. SAMET: You're better than your colleague.

DR. LOOMIS: I'm speaking directly into my handset.

DR. SAMET: All right. Thank you.

DR. LOOMIS: Thank you very much. It is my pleasure to present to the committee today. I'm Brett Loomis. I'm an economist at RTI International, and the topic of my talk today is trends in prices, sales, and promotions for menthol cigarettes in the United States.

But first, this disclaimer. The information in the following presentation is not a formal dissemination of information by FDA and

does not represent an agency position or policy. The information is being provided to TPSAC to aid the committee in its evaluation of the issues and questions referred to the committee.

Earlier this year, RTI was contracted by FDA to provide an economic analysis of the market for menthol cigarettes in the United States. To do this, RTI is using retail scanner data from the Nielsen Company to understand the trend in menthol cigarette sales, including the volume of sales, which is the dollar sales as well as unit sales; market share for menthol and non-menthol cigarettes alike; the price per pack; and promotion of cigarettes, including the percent of all sales that are promoted, as well as the types of promotion that appear in the data.

For this specific report, RTI purchased or licensed 104 weekly periods of data from Nielsen, beginning from the week ending August 16, 2008 and extending through the week ending July 16, 2010. The data you'll see today covered two retail channels, convenience stores as well as

food stores, drugstores, and mass merchandisers combined. Later in the talk, I'll define those channels more specifically. I'll be presenting data for the total United States for menthol and non-menthol cigarettes combined.

In addition to that, RTI has in its possession a longer-term series of data from Nielsen that goes back to the first quarter of 1994 and extends through the third calendar quarter of 2010. This data is from food stores only. It covers the total United States, and we can present trends for menthol and non-menthol cigarettes from this longer span of data as well.

So before I begin presenting results, I think it's useful to take a brief orientation to the Nielsen scanner data. Scanner data is relevant and useful, but it does have some unique characteristics that are important to understand in order to interpret the results appropriately.

So how does Nielsen collect its data? When an individual purchases cigarettes at the store, they take them to the cash register where

they are scanned. The electronic scanner reads the bar code on the package of cigarettes. The number from the bar code is looked up in a database that resides on a computer in the store.

The database contains information about the product type and characteristics; for example, they're cigarettes, the brand name, the sub-brand name, and other characteristics of the cigarettes such as length, menthol or not, and things like that. The database has a price, which is what the consumer is charged, and it's also linked with the universal product code.

Nielsen aggregates all of these store-level transactions by cigarette category, also by brand and UPC code and channel and market area, and then uses that information to create what they call a market projection for the item based on the data.

Now, to follow the chain of how this works, perhaps in a single week there might be 200 units of a particular cigarette variety sold in a given store. And then, as Nielsen aggregates all

of the data from stores in a given area, there might be 9,000 units of those sold in Nielsen's sample of stores over its market area.

Nielsen will then model, using proprietary methods, that perhaps there are 15,000 units of that particular cigarette variety sold in the market in consideration, and it's that market projection that is supplied to users of the data like RTI.

Now, the example I just gave is hypothetical. It's not based on actual numbers supplied by Nielsen. I just gave it to illustrate that the data we are using and presenting today are estimates of sales, prices, and promotions for all cigarettes sold and not sample data from a subset of stores. So, in effect, the data we're looking at is population data and not sample data.

Now, Nielsen provides its data for various retail channels. I mentioned them earlier. There are convenience stores, food stores, drugstores, and then a combined food, drug, and mass category.

The convenience store trade channel is defined using a definition that's endorsed by the National Association of Convenience Stores. It includes small format stores that are between 800 and 3,000 square feet, with between 500 and 1,500 unique products, that are open for at least 13 hours a day and carry a limited selection of grocery items. Okay? Examples of convenience stores include stores like 7-Eleven and Mobil Mart. Okay? The convenience stores may or may not sell gasoline, and they may or may not offer fast food service as well.

Food stores can be thought of as grocery stores. They include conventional supermarkets, which would be full-service, full-line grocery stores with annual sales of $2 million or more; limited assortment supermarkets that would carry a smaller or reduced number of categories that might be all natural products, gourmet quality, or special pricing. Examples of those kinds of stores are Trader Joe's. And they also include supercenters such as Meyer Supercenter.

Drugstores are stores that sell prescription pharmacy items and health and beauty care products. They include stores like Rite-Aid and CVS.

Mass merchandisers are large format, often known as discount stores, that are very large, 40,000 to 160,000 square feet, typically, in a single-level structure, and examples include Wal-Mart, KMart, and Target. However, in the mass merchandiser data offered by Nielsen, Wal-Mart is not included.

In addition to these channels, Nielsen offers its data over geographic defined market areas. These market areas are collections of counties. They usually contain at least one large metropolitan area. For the food channel, which has the largest number of market areas, the average number of counties is 30, with a range of one county to a maximum of 79 counties. The average population is about 4.6 million people, with the minimum population being 1.1 million and the maximum population being 20.3 million.

So market areas are typically quite large. They often do not conform to convenient geographic units such as metropolitan statistical areas, and they often cross state borders, which can be problematic for analysis.

The number of market areas differs by channel. So if you're interested in convenience store data, there are 25 markets. There are 52 markets for the food channel, 11 markets for the drug channel, and 10 markets for the combined food, drug, and mass channel.

I mentioned earlier that Nielsen uses a projection-type methodology to project total sales within a market area. In a similar way, Nielsen combines all of the data from its defined market areas for each channel to project what sales prices and promotions are for the total United States.

This slide here is a map of the United States with state and county borders drawn in. It has the 25 defined convenience store market areas shown in green with a yellow border. You can see

that some of the markets are quite large -- for example, the Phoenix market consists of the entire state of Arizona -- while other markets are fairly small geographically. If you look at Chicago, the southern end of Lake Michigan, you'll see that it is fairly small geographically. However, there is reasonable coverage across the four major regions of the United States, including the Northeast, the South, the Midwest -- and the Midwest.

This is a map of the United States, as before, with the 10 combined food, drug, and mass markets highlighted in purple with a yellow border. Coverage for this channel is focused on the Northeast in the United States.

This slide presents the map of the United States, as before, with the Nielsen-defined food market areas in light blue with a yellow border. The 52 food market areas cover the largest proportion of the United States and include about 72 percent of the U.S. population as of 2010.

So that covers a little bit about how Nielsen collects and prepares its scanner data and

what's available to the user. So let's turn our attention to what is actually in the scanner data that we get.

RTI receives UPC-level scanner data, which is the finest level of data that is available. It includes the various item characteristics for cigarettes, such as the brand name, which might be Marlboro, for example; the sub-brand, which would include information about light or mild or ultra-light or any other kind of sub-brand information that's included on the pack; the length of the cigarette in millimeters; whether the cigarette is filtered, yes or not; whether it's menthol, yes or not; the unit size -- sometimes cigarettes come in packs of other than 20 cigarettes; the packaging type -- it could be a pack, a carton, a half-carton, or multiples of packs, as well as hard packs and soft packs -- and the deal, which is a variable that measures promotions.

There are three kinds of promotions that come with the scanner data. There's the buy one,

get one free promotion, there are cents-off promotions, and gifts with purchase promotions.

In order for these kinds of promotions to appear in the scanner data, they have to be associated with a unique universal product code, and that is not always the case. So the figures that I'll report later on the percent of sales that are reported would tend to underestimate the total amount of discounting and promotions that occurs in the cigarette market.

The facts that are associated with each item in the data set include the dollar volume or the total dollar sales associated with that unit in a particular time, in a particular market, and the number of units sold.

So in the box, you see an example item listing. This is taken directly from the data that appeared to us. Reading it from left to right, the CML stands for Camel; the M is menthol; F is filtered; 85 is an 85 millimeter length cigarette, so it's a king-sized cigarette; BX means those cigarettes come in a box as opposed to

hard pack; and the P2P 1-1 is a code for promotion. It's a promoted item. There are two packs. You buy one, get one free. And then the 20 count, that equals 20 count, tells us that there are 20 cigarettes in each one of those packs.

For that particular item, Nielsen would report the dollar sales, the unit sales, a universal product code -- and the universal product code as well.

From the measures that Nielsen reports, we are able to calculate a standard quantity, which is one 20-cigarette pack. As I mentioned earlier, some units come in other-than-20 cigarettes per pack, and so we standardize all of our pack counts to 20-cigarette packs.

We can calculate the price per unit by dividing dollar sales by unit sales. We calculate the price per pack based on the standard quantity. We can sum up sales across different types of units and brands, and come up with a market share estimate for that. And we can look at promotions.

We can look at the sales associated with each kind of promotion, the price associated with the promotion, as well as the market share or the percentage of all sales associated with any given promotion.

So moving on to methods, the data that we received from Nielsen came to us in spreadsheet form. They sent us 102 spreadsheets, or 1,396 tabs. All of those tabs had to be edited for conformity, and then we imported them into Stata 11 statistical software, which is running on a Linux-based server here at RTI.

We do all of our processing in Stata, and we run all of our programs in batch mode so that there is a log file of all changes made to the data and all analyses that are run. Nothing is done interactively. We combine the data from all the tabs and all the markets to a single analytic data file.

We are able to parse the item string that I mentioned earlier so that we can flag brands, sub-brands. We can separate cigarettes out by

strength. We are able to separate menthol cigarettes from non-menthol cigarettes, filtered, by length and tar level, et cetera.

We code variables to identify the promotions, including the type of promotions and sales, and we use the packaging details in the item string to calculate the standardized unit of sale, which is the single 20-cigarette pack that I told you about. All prices are adjusted for inflation, and we have an extensive battery of quality checks that we run on the data to make sure that everything is processed correctly.

So in order to generate a measure of total sales, all we have to do is sum up all of the pack sales in the data. We can do that by time period, by market, or for the total United States. The price per pack is simply the dollar sales for a given unit divided by the pack sales for that given unit, adjusted for inflation.

The market share for menthol cigarettes is just the sum of all pack sales for menthol cigarettes divided by all pack sales. The market

share for promoted cigarettes is just the pack sales for cigarettes that were flagged as being promoted divided by all pack sales. We can do this by retail channel, for time period, and by type of cigarette, for menthol and non-menthol cigarette alike.

Now, I mentioned earlier that the data that Nielsen reports is essentially population data because they use a propriety method to project from the market level to -- from their sample to the market level. So we're treating the data as population data and not sample data.

Because of that, we don't do any statistical testing on the data. We don't generate any confidence intervals, nor do we make any kind of statistical comparisons across time or between markets. We can just look at the data and see if there's a difference.

So let's get to our results. From the 104 weekly periods of data that I mentioned we purchased for this project, we were able to identify 195 cigarette brand families; 154 of

those, or 79 percent of them, had at least one variety of menthol cigarette.

We were able to identify 1,401 individual varieties of cigarettes. 512 of them, or 36 and a half percent, were menthol. We defined a cigarette variety as being a combination of a cigarette's brand, sub-brand, tar level, length, and whether it was filtered or menthol. That would include clove cigarettes as well.

This chart lists the top 10-selling cigarette varieties in the United States by dollar sales over the two-year period from August 16, 2008 through July 16, 2010. The results are for the total United States over that time period, and combine the food, drug, and mass and convenience store channels.

The top-selling brands are Marlboro Lights, 85 length, 85 king-sized, non-menthol cigarettes, for $18.2 billion in total sales over that two-year period. Menthol cigarettes are -- three of the top 10 cigarette varieties are menthol. Number three is Newport, with

$6.6 billion in sales over that two-year period. The next menthol variety is another Newport variety, with $3.8 billion in sales. And the number 10, top 10-selling cigarette variety is Marlboro, menthol variety, with $2.4 billion in sales over the two years.

This chart lists the top 10-selling menthol varieties. You can see that Newport and Marlboro have the top five spots locked up. The number one brand, Newport, full strength, 85 millimeter, is far and away the most popular menthol variety, with $6.6 billion in sales over the two-year period.

DR. SAMET: Brett, sorry to interrupt. Just watch the time. How many more slides do you have, roughly?

DR. LOOMIS: Well, I have approximately 20 more slides, but as I click through them, I don't see any of the data.

DR. SAMET: Oh, I don't, either.

DR. LOOMIS: They're all blank. I have the presentation on my computer. I can share my

desktop.

DR. SAMET: I wonder -- yes. We are nearing the end of what should have been your presentation time. We were sent slides this morning. I don't know -- let me pull up what came and see if yours were -- let's see if they are -- if we have the right stuff. Those who have access to computers might be able to look.

DR. HECK: Yes. Mr. Chairman, the ones I received were intact. Daniel Heck.

DR. SAMET: Okay, Dan. Thanks. Yes. For those of us who have access to our computers, as Dan pointed out, the slide sets that were sent this morning do have the data included. So we could either, with your guidance, Brett, click through -- perhaps we could do that, and perhaps somebody could be fooling around with your computer to see if they could get the slides up.

So you were at slide 22, I think. Correct?

DR. LOOMIS: Yes. I'm currently at slide 22. I can share my computer screen, and I can pull

up the presentation on my computer screen. And then everybody should be able to see if it I do that.

DR. SAMET: Okay, relatively quickly.

MS. COHEN: We can see the graphics here in this room.

DR. LOOMIS: All right. Here we go.

MS. COHEN: We're working on trying to get everybody to be able to see this. Can you see the graphics on your --

DR. SAMET: Yes. I can see it. Yes, it is back now.

MS. COHEN: Okay.

DR. LOOMIS: Okay. I'll go through these quickly, and then we can have our break. I think everybody probably has to --

DR. SAMET: Well, I want to make sure there's time for questions, actually.

DR. LOOMIS: All right. This chart, chart number 22, shows weekly cigarette pack sales. The top line is weekly cigarette pack sales in convenience stores. The bottom line, the

blue line, is pack sales in food, drug, and mass combined.

Along the bottom axis, even though it's not labeled as such, are the weeks. It starts at 8/16/08 and goes through July 16, 2010. And along the vertical axis is packs sold per week in millions. So in August 16, 2010, that week ending, there were a total of 269 million packs sold, 232 million from convenience, 37 million from food, drug, and mass.

There was somewhat of a decline of approximately 10 percent by the end of the period. At the end of the period, there were 242 million packs sold per week, 209 million of them coming from convenience stores and 33 million coming from food, drug, and mass. Next slide, please.

Slide 23 shows the percent of those sales that were menthol. In convenience stores, there were between 25.1 percent and 27 percent of all sales of cigarette sales were menthol, and in food, drug, and mass stores, they were between 24.5 and 25.7 percent of total sales that were

menthol. So menthol sales do appear to be increasing slightly over this period, but the sales of menthol cigarettes are comparable across the two channels. Next slide, please.

This is a chart of the long-term trend for menthol cigarette sales from the food channel. In 1994 in grocery stores, menthol accounted for 24.5 percent of all cigarette sales. By third quarter of 2010, they had declined slightly to 22.6 percent of sales in food stores. Next slide, please.

This chart shows the average inflation-adjusted price per pack of cigarettes between August 16, 2008 and July 16, 2010 for convenience stores and food, drug, and mass combined. At the beginning of the period, in August of 2008, the prices were basically the same, $3.73 per pack in both convenience stores and drugstores. By the end of the period, in July of 2010, it was almost virtually the same. It was $5.03 per pack in convenience stores on average, $5 per pack in food, drug, and mass on average.

The horizontal line shows approximately the location of the April 1, 2009 federal cigarette excise tax increase. You can see by the jump in the price series there the impact that raising that tax had on retail prices. Quite notable. Next slide, please.

This shows the average price for menthol and non-menthol cigarettes in the food, drug, and mass channel. In August of 2008, menthol cigarettes were approximately 12 cents more expensive than non-menthol cigarettes, and at the end of the time period, in July of 2010, menthol cigarettes were still more expensive by about 13 cents compared to non-menthol cigarettes. So menthol cigarettes do appear to be slightly more expensive in food, drug, and mass than in convenience stores.

Can you please advance the slide.

This shows the real price per pack of menthol versus non-menthol cigarettes in convenience stores. Again, we see that menthol cigarettes are slightly more expensive than non-

menthol cigarettes over the entire time period shown. There is a 6-cent differential at the beginning of the series, August 2008, and by the end of the series, that had expanded to 13 cents per pack difference, where menthol being more expensive than non-menthol cigarettes. Next slide, please.

This shows the long-term trend in the price per pack of cigarettes for menthol versus non-menthol. This is the real price per pack -- it's been adjusted to 2009, inflation-adjusted -- in the food stores. In 1994, $2.24 on average for a pack of menthol cigarettes and non-menthol cigarettes alike. By the end of the time period in 2010, menthol cigarettes had become 14 cents more expensive, on average, than non-menthol cigarettes. Next slide, please.

This slide shows the percent of total sales that are promoted for convenience stores and food, drug, and mass. The red line is convenience, the blue line is food, drug, and mass. This is for all cigarette sales.

At the beginning of the period, you can see there's about 4.43 percent of all cigarette sales from convenience stores were promoted, compared to just over 1 and a half percent of cigarette sales at food, drug, and mass. The general trend is upward. By the end of the period, close to 6 percent of sales were promoted in convenience stores, and 2.7 percent of sales were promoted in food, drug, and mass, although it is quite variable over the time period, as you can see there. Next slide, please.

This shows the percent of all sales that are promoted for menthol and non-menthol cigarettes in the food, drug, and mass category. In general, sales of promoted cigarettes is generally higher in the menthol category versus the non-menthol category over the entire time period. Next slide, please.

This is the percent of sales that are promoted for menthol and non-menthol cigarettes in convenience stores from August 2008 through July of 2010. In general, menthol cigarettes have

higher promoted sales than non-menthol cigarettes in convenience stores, although this is not always the case. You can see in the first half of the series that there are plenty of weeks when there are more non-menthols being sold under promotion than menthol cigarettes, and the variability is quite pronounced. Next slide, please.

This is a long-term trend of promoted sales for menthol and non-menthol cigarettes from food stores in the United States. In the early part of the series, in 1994, '95, '96, '97, you can see that promoted sales were quite low. After the master settlement agreement in 1998 and 1999, promoted sales increased somewhat for both menthol and non-menthol cigarettes. At the time, it was considered a very large increase in promoted sales. It was dwarfed by the spike in promoted sales in 2002 and 2003 for non-menthol cigarettes.

After 2003, you can see that promoted sales for menthol cigarettes increased steadily, while promoted sales were -- excuse me. Promoted sales for menthol cigarettes increased steadily,

while promoted sales for non-menthol cigarettes stayed basically flat. And there was a decline in 2009, and now they're just about equal in 2010. So promoted sales for menthols and non-menthols over time have been increasing.

Let's see. This chart here shows the various types of promotions for menthol cigarettes in the food, drug, and mass channel by week. The green area -- the blue area, excuse me, shows the percent of sales that are accounted for by buy one, get-one-free type offers. The red part, which is quite slim, is the percent of promoted sales accounted for by item giveaways, such as buy a pack, get a lighter. And the green area shows the percent of those that are accounted for by straight-up price discounts, such as the 50-cent price discount per pack. In the early part of the series, buy one, get one free were more prevalent than in the later part of the series, when they had virtually disappeared. Next slide, please.

This shows promotions for non-menthol cigarettes in food, drug, and mass. The blue area

is buy one, get one free, the green area are cents off, and the red area are buy one, get a gift with purchase. Again, for non-menthol cigarettes, we see that buy one, get-one-free type offers disappear almost completely in the later part of the series compared to the beginning part of the series. And the relative frequency of buy one, get-one-free type offers is much more common for non-menthol than for menthol cigarettes. Next slide, please.

This shows promotions for menthol cigarettes in convenience stores. The blue are buy one, get-one-free type offers. You can see that in the early part of -- well, in the last half of 2008, early part of 2009, buy one, get-one-free offers were much more prevalent for menthol cigarettes in convenience stores than they were in the last half, in the last two-thirds of the time frame. Next slide, please.

This shows the type of promotions for non-menthol cigarettes in convenience stores. Just like for menthol cigarettes, buy one,

get-one-free type offers were much more prevalent than they used to be, and between August of 2008 and February of 2009, buy one, get-one-free offers accounted for almost all promotions for non-menthol cigarettes in convenience stores. By the end of 2009, early 2010, it was cents-off type promotions that accounted for almost all promoted sales for non-menthol sales in convenience stores. Next slide, please.

Okay. So just to run through a few conclusions that we can draw from all of this information, menthol cigarettes are certainly popular, with three of the top-10 selling cigarette varieties. Convenience stores sell six times as many cigarettes as food stores, drugstores, and mass merchandisers combined, yet the proportion of sales that are menthol is similar across both of those channels.

The long-term trend in menthol sales from the food channel is pretty stable, between 22 and 24 percent total sales, which is consistent with what we see in the near-term trend from

convenience stores and food, drug, and mass.

Cigarette prices are increasing steadily, with menthol cigarettes being slightly, though consistently, more expensive than non-menthol cigarettes by approximately 2 to 3 percent. Next slide, please.

Promoted cigarettes account for a greater proportion of total sales in convenience stores than in the food, drug, and mass category. Promoted cigarettes account for a generally greater proportion of sales for menthol cigarettes compared to non-menthol cigarettes in both convenience stores and food, drug, and mass.

The long-term trend in sales of promoted cigarettes in grocery stores shows high variance over time, and the mix of promotions has changed recently, with buy one, get-one-free type offers being much less common than cents-off offers in the past year.

At this time, I'd like to briefly acknowledge my colleagues, Andrew Busey, Doris Fuller, Nathan Mann, and Matthew Farrelly.

Without their assistance, this presentation would not have been possible.

DR. SAMET: Thank you. Thanks, Brett.

We are a little bit behind. We've heard, I think, a lot of very interesting data. We have a public comment period ahead, and I believe we have six commenters. So what I'm going to ask is that clarifying questions be very explicit and brief.

Greg, explicit and brief. Go ahead. Greg?

AUTOMATED VOICE: The conference is now in silent mode.

[Laughter.]

DR. CONNOLLY: Hello? Can you hear me? Hello?

MR. GRAHAM: We hear you.

AUTOMATED VOICE: The conference is now in talk mode.

DR. CONNOLLY: Can you hear me?

DR. SAMET: Hang on a second. Tom, are we all set with this?

MR. GRAHAM: We are good to go.

DR. SAMET: Okay. And just again, I want just brief clarifying comments because of the time here.

DR. CONNOLLY: Okay. Briefly, we found a lot of problems with the cleanliness of the Nielsen data, and actually going back in and clarifying what they were claiming to be menthol versus non-menthol. What were your data cleaning procedures?

DR. LOOMIS: We have extensive data cleaning procedures that we've developed over the past eight years in working with Nielsen data. If you want, maybe that's something that we can follow up with you online.

DR. CONNOLLY: Okay. Second point is, price promotions are interesting; but we did a study looking from '96 to 2004, and we found menthol advertising through MRI data sets to be extremely high versus non-menthol brands.

Have you looked at the MRI data sets?

DR. LOOMIS: We have not.

DR. CONNOLLY: Your study was a study that lasted one year and three quarters. If you go back in and you look at the data prior to that, it only includes 20 percent of market, that being pharmacies and probably food chains.

Do you think those two samples are comparable?

DR. LOOMIS: I think they're comparable in some respects, yes.

DR. CONNOLLY: Did you see any change in UPCS codes when the law went into force requiring a ban of menthol descriptors -- I mean, light descriptors on menthol brands? Did you see a change in the UPC codes? Did you take that into account?

DR. LOOMIS: No. We did not see any change in the UPC codes. In fact, we still see those descriptors appearing in the Nielsen data. I think it's because -- well, I could speculate on the reason for that, but I won't at this time.

DR. CONNOLLY: Okay. I'm just making observations. We're looking at one year and three

quarters of data, and I think that should be taken into account. Thank you.

DR. SAMET: Melanie?

DR. WAKEFIELD: Yes. Thanks, Dr. Loomis, for your presentation. I just wanted to clarify that the slides that you put up showing real price per pack, is that the price after the promotions had been taken -- is it the price paid after the promotions had been taken into account, or could you just clarify what that is?

DR. LOOMIS: Yes. Yes, that's true. Promotions have been taken into account there.

DR. WAKEFIELD: Okay. Thank you.

DR. SAMET: John? John Lauterbach?

DR. LAUTERBACH: Okay. Can you hear me now?

DR. SAMET: Yes.

DR. LOOMIS: Yes.

DR. LAUTERBACH: With most of the small manufacturers being only non-menthol, or very much non-menthol, does that skew your data in any way in terms of any of these percentages?

DR. LOOMIS: No, I don't think so, because we're summing over all cigarette varieties. So to the extent that the small -- the varieties produced by small manufacturers are in the data, then they're represented according to their weight in the market.

DR. SAMET: Cathy? Cathy? I wonder if we lost her. Cathy Backinger?

DR. BACKINGER: Hello?

DR. SAMET: Yes.

DR. BACKINGER: I'm sorry, but there's a little bit of a delay when we're unmuting our phones.

Here's my quick question, and I'm assuming, and I don't know all the methodologies for using Nielsen data. But given that you presented showing the maps of where the data are collected by state and county, I'm wondering whether you can do further breakdowns by -- at probably the county level or even less, about in communities that are more primarily African American, to look at the price differential for

both menthol and non-menthol in those communities compared to non-African American communities as well, with the actual amount of the price cents -- the price discount is, and also maybe the type of discount.

Is that possible?

DR. LOOMIS: Well, the lowest level of geographic unit that I would want to report these data for is the market area, and you saw how big some of those market areas are on the map.

DR. BACKINGER: Yes.

DR. LOOMIS: In the report that we intend to submit to FDA in December, it will have market-by-market breakdowns.

DR. BACKINGER: Then we can -- from census data, then we could find out, then -- to at least make a comparison as far as percentage of different rates' ethnicities in those market areas?

DR. LOOMIS: Yes. That's quite possible.

DR. BACKINGER: Thank you.

DR. SAMET: Okay. I don't see anybody

else's hand up. We are behind. We are scheduled for a break at this point. I'm going to suggest that if we take a break -- let's see, I've got about 10 after -- that we reconvene in 10 minutes because of where we are.

Actually, looking at the room, Corinne, can you make sure we're ready to go in 10 minutes? I think last time we did this on one of these calls, we were quite delayed in getting back together. So let's make it 10 minutes.

DR. HUSTEN: We'll start in 10 minutes whether everybody's here or not.

DR. SAMET: Okay. All right. Ready, set, go.

MR. GRAHAM: Please do not hang up on the phone.

(Whereupon, a recess was taken.)

Open Public Hearing

DR. SAMET: We're moving on to the open public hearing. And as I begin it, I want to make introductory remarks.

Both the Food and Drug Administration, or

FDA, and the public believe in a transparent process for information-gathering and decision-making. To ensure such transparency at the open public hearing session of the advisory committee meeting, FDA believes that it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with a sponsor, its product, and if known, its direct competitors.

For example, this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not

preclude you from speaking.

The FDA and this committee place great importance in the open public hearing process. The insights and comments provided can help the agency and this committee in their consideration of the issues before them.

That said, in many instances and for many topics there will be a variety of opinions. One of our goals today is for the open public hearing to be conducted in a fair and open way where every participant is listened to carefully and treated with dignity, courtesy, and respect. Therefore, please speak only when recognized by the chair. Thank you for your cooperation.

I'll also point out that each speaker is limited to 10 minutes for their presentation. And I guess, Karen, they will have a light indicating the time; is that correct?

MS. COHEN: Yes.

DR. SAMET: I'm sorry?

MS. COHEN: Yes. Yes, we will be timing them with a light.

DR. SAMET: So I'll be watching, but, speakers, please limit your presentation to 10 minutes. And then, if the committee has questions, they will follow.

So our first presenter is Jonathan Winickoff, representing the American Academy of Pediatrics. Jon?

DR. WINICKOFF: My name is Dr. Jonathan Winickoff. I'm a practicing pediatrician and associate professor at Harvard Medical School. My research focuses on tobacco control in child healthcare settings, and child secondhand smoke exposure. I have no relevant financial relationships to disclose.

I'm here today in an official capacity, representing the American Academy of Pediatrics, the AAP, as a member and past chair of the AAP Tobacco Consortium, and as a principal with the AAP Julius B. Richmond Center of Excellence.

The AAP is a nonprofit professional organization of more than 62,000 primary care pediatricians, pediatric medical subspecialists,

and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

The AAP welcomes this opportunity to address the Tobacco Products Scientific Advisory Committee. The Food and Drug Administration has a vitally important role to play in protecting children and adolescents from the harms of tobacco, and this committee's guidance will be essential to this effort.

The AAP recognizes the substantial dangers of tobacco use and secondhand smoke exposure to children's health. Tobacco control was named a strategic priority by the AAP in 2005, and the Julius B. Richmond Center of Excellence, dedicated to the elimination of children's exposure to tobacco, was established in 2006 to foster tobacco control research and initiatives at the AAP. The Richmond Center has allowed the Academy to pursue numerous research projects, one of which we will share with you today.

The mission of the Richmond Center is

accomplished by changing the clinical practice of pediatrics through the development and dissemination of practice tools, research, healthcare systems change, and improvement of community health. Our vision is that all child healthcare clinicians will be active participants in the elimination of tobacco and secondhand smoke exposure of children. Pediatric clinicians are well-positioned to counsel parents about reducing secondhand smoke exposure in a repeated and consistent manner and can provide critical support for community policy changes that help protect children.

The Richmond Center works to create a healthy environment for children, adolescents, and families through public education and the promotion of public health policies to eliminate tobacco. The Center helps provide child health clinicians with education, training, and tools needed to effectively intervene to protect children from the harmful effects of tobacco and secondhand smoke.

Today we'd like to share with the committee new data available on public attitudes toward the regulation of menthol cigarettes. Menthol is particularly troubling to the public health community, and Congress did not explicitly ban its use along with the prohibition on other cigarette flavors.

The role of menthol in facilitating smoking initiation is greatly concerning. Our nation's youth smoke menthol cigarettes at higher rates than older smokers. While a child's first cigarette is usually an unpleasant experience, menthol can make it less so, partially by anesthetizing the throat against the harshness of tobacco smoke.

As Carol McGruder, co-chair of the African American Tobacco Control Leadership Council explained, "Menthol is not just a flavorant. It makes it easier for our youth to start smoking, it keeps people smoking, and it inhibits them from quitting. Menthol makes the poison go down easier."

Our new data comes from the Social Climate Survey of Tobacco Control, an annual cross-sectional survey on attitudes regarding tobacco and tobacco regulation. Support for the survey was provided by the Flight Attendant Medical Research Institute and the American Legacy Foundation. While this research has been submitted for publication, we felt it important to share the data with the committee before it completes its work addressing menthol cigarettes.

With the 2009 Social Climate Survey results, we now for the first time have scientific data on public attitudes towards banning cigarettes with menthol and other flavors, both among the general population and specifically in the African American community. Since 82.6 percent of African Americans smoke menthol cigarettes, it was important to gauge the attitudes of this particular population.

The national survey was conducted using rigorous random digit dial survey methodology, and polled 1,514 people in the initial sample. An

additional sample of 303 African Americans was later obtained to allow us to make stronger statistical inferences about this population.

We asked respondents whether they strongly agreed, agreed, disagreed, or strongly disagreed with two statements: Cigarettes with added flavorings, like cherry, chocolate, lime, and mint should be prohibited; and, two, menthol cigarettes should be prohibited, just like other flavored cigarettes. We also asked respondents a series of questions to determine whether they were current smokers, former smokers, or never smokers.

Overall support for banning flavors was 70.2 percent, and support for banning menthol specifically was 56.1 percent. Among African Americans in the additional sample, there was 78.8 percent support for banning flavors, and 75.8 percent support for banning menthol specifically.

Even current smokers were not universally opposed to banning flavors. Overall, 43.1 percent of current smokers supported banning flavors generally; 28.4 percent supported a specific ban

on menthol. Among African American smokers, in the additional sample, 57.4 percent supported banning flavors and 52.8 percent favored banning menthol.

Data on smokers who themselves smoke menthol cigarettes were even more surprising. Of the 97 menthol smokers in the main sample, a full one-fifth, or 20.6 percent, wanted menthol cigarettes, their chosen product, banned. Of 44 menthol smokers in the additional sample of African Americans, roughly half, or 47 percent, wanted menthol banned.

In sum, the results clearly show that the American public strongly favors a ban on menthol cigarettes. This result is consistent among both whites and African Americans.

The tobacco industry has argued that the continued availability of menthol cigarettes protects the user preferences of a specific demographic group. This argument is completely undercut by these data, which show that not only do an overwhelming number of African Americans

favor a menthol ban, but even a majority of current African American smokers support removing menthol from cigarettes. Moreover, almost half of African American menthol smokers want their own preferred product banned.

This may reflect an acknowledgment of the particular disease burden experienced by this community as a result of menthol cigarettes and may also reflect a desire among current menthol smokers to quit. We would also expect that as efforts continue to educate the public about the impact of menthol cigarettes, particularly on youth, the number of those who favor a menthol ban will only rise. We ask both this committee and the FDA to be cognizant of these data when considering policy responses to the problem of menthol cigarettes.

At this committee's first meeting in March, the AAP applauded FDA for removing flavored cigarettes other than menthol from the market. We further stated our opposition to all flavored tobacco products, including mentholated products,

due to their attractiveness to children and adolescents and their impact on smoking initiation.

Today, we reiterate our call for FDA to swiftly remove from the market all flavored tobacco, including menthol cigarettes, flavored cigars, flavored cigarillos, and flavored smokeless tobacco products. The sole exception to this prohibition should be nicotine replacement therapies that are approved by the FDA.

Because children are a vulnerable population, it has always been the position of this AAP that when it comes to protecting them from dangerous products, the burden of proof must always favor the health and well-being of children. In our view, there is more than sufficient evidence of menthol's harm to justify its removal from the market, and the American public agrees.

Thank you for the opportunity to speak to you today.

DR. SAMET: Thank you.

Let's see if we have clarifying questions from the committee. Melanie?

DR. WAKEFIELD: Yes. Just a quick question.

It's helpful, I think, to see some representative population data on this. Could you just clarify what the response rate for the survey was? I think that's quite important to know.

DR. WINICKOFF: Yes. We had two survey samples. In the first sample, of 2,560 eligible respondents contacted, we had 1,514 completed the survey, so a 59 percent response rate. And in the over-sample of African Americans of 427 eligible African Americans contacted, 303, or 75.7 percent, completed the survey.

DR. WAKEFIELD: That's pretty respectable. Thank you.

DR. SAMET: Thank you.

Greg? Let's see. Greg?

DR. CONNOLLY: Jon, could you share with the FDA the methods and the raw data? And did you over-sample black smokers in your survey?

DR. WINICKOFF: Yes. We did have a second sample, Greg, of African Americans, realizing that this was a group of particular interest and importance. So there are two specific samples, one general sample and then an additional sample focused on African Americans.

DR. CONNOLLY: Is it possible to go back and re-survey with an over-sample of African American smokers?

DR. WINICKOFF: Yes. Actually, that was the reason why we did the 303 sample of African Americans, and this is a nationally representative sampling of that group.

DR. CONNOLLY: But were these smokers -- were the African American smokers over-sampled so that -- and if you didn't, could the Academy go back in and do an over-sample of minorities?

DR. WINICKOFF: Yes. Yes, we could get more African American smokers, if that were funded appropriately.

DR. SAMET: Mark? Let's see. Mark?

DR. CLANTON: Can you hear me?

DR. SAMET: Now we can, yes. Go ahead.

DR. CLANTON: Yes. I'm having some trouble with you on and off, but I apologize.

My question has to do with an even more amplified paradox, I guess. The industry has testified and maintains that adults who smoke menthol cigarettes do so because they like the taste and for no other reason. But your data talks about African Americans who are smoking menthol cigarettes being in favor of a ban of even their own brand of cigarettes.

I'd like to give you an opportunity to maybe expand and maybe speculate further why in the world that would be the case if, in fact, taste is the only reason people pick these cigarettes and smoke them.

DR. WINICKOFF: I can think of two reasons. I think it reflects a desire to quit smoking, and I think it reflects a desire to ensure that their relatives, their children, are no longer targeted and addicted by a mentholated product that eventually will kill half of all

those who use it.

DR. CLANTON: So it appears that your sense is that there's more than taste involved in menthol, that there's some measure of dependence as it relates to both the menthol and the nicotine blend?

DR. WINICKOFF: Yes, more than taste.

DR. CLANTON: Thank you.

DR. SAMET: Dan?

DR. HECK: Yes. Thank you for your comments, sir. May I ask, is the full script of the telephone survey that you conducted available, and can it be made available to the committee?

DR. WINICKOFF: Yes. It's online.

DR. SAMET: Jack?

DR. HENNINGFIELD: I just -- am I off mute?

DR. SAMET: Yes. You're good.

DR. HENNINGFIELD: Okay. I just want to comment. The ambivalence or even opposition of many users of these products is not completely surprising from just what we know about addiction

in a general perspective. And it's frequently the case that people who are addicted to opioids, stimulants, and other drugs also would love to see themselves unable to get those products.

So while it may seem surprising to some that some menthol smokers would like to see the products banned, again, from a general addiction perspective, that's not surprising. And in writing up the report, the thoughts of, again, other addiction experts on this panel like Drs. Westley Clark and Hatsukami will be helpful.

DR. SAMET: Greg, did you have your hand up again?

[No response.]

DR. SAMET: Okay. Are we done? Let's see. I think we'll move on to our next speaker, then.

If we can move to the next speaker, Frederick Flyer from Compass Lexecon. Go ahead, please.

DR. FLYER: Hi. I'm Frederick Flyer from Compass Lexecon, and we are an economic consulting

group that has been retained by Lorillard to conduct an economic analysis on the potential size of the black market for menthol cigarettes that might emerge if a ban were implemented.

Let me tell you a little bit about our group, my expertise and the others who worked on this project. We typically work on merger assessment and commonly predict pricing associated with mergers. I've worked on the Whirlpool/Maytag merger, other large mergers that have gone up for antitrust review. And I've also worked for the government on a number of cases to assess mergers.

What we've been asked to do is to assess the size of the market, pricing in that market, and other aspects of the market. And we use the approach that we typically use in merger analysis. And, specifically, that approach relies on the fundamental economic tools of demand and supply. So we essentially try to look at --

[Pause]

DR. FLYER: What I was saying is we try to use the methods of estimating demand and

supply, and to see -- really, to answer two basic questions. One is, what would the black market for menthol cigarettes look like in terms of size; and, secondly, to understand, once we make that prediction, what the likely effects would be on aggregate smoking in general.

I want to say that that's a very difficult task, and our work is still ongoing. So, hence, what we report today are preliminary results, and there's a paper that we anticipate finishing within the next month that we will provide. There's also much uncertainty in all of the analyses, but we think there are some fundamental aspects, economic aspects, that come through from the analysis. And we'll touch on some of that, and touch on some of the predictions on the size of the market that come from our review --

[Speaker adjusts microphone.]

DR. FLYER: Is this better?

DR. SAMET: That's better.

DR. FLYER: So we're going to touch a

little bit on the aspects of the analysis that we think will point to, when looking at the market, what type of contraband market would emerge, how large it would be. And I think we've identified key parameters, even though we have uncertainty in terms of our parameter estimates, specifically on the supply side because much of the market, what it will look like will depend on the flow of contraband cigarettes. And that's a subject that really has much uncertainty associated with it.

But anyhow, to start the analysis, it may be helpful to think about the three choices a current menthol smoker would have post-ban. One choice would be to quit smoking. The second choice would be to shift to non-menthol cigarettes. And the third choice would be to source menthol cigarettes, and presumably source those cigarettes on the black market, although there may be other ways to source those cigarettes.

So given those three buckets that a smoker could potentially -- a current menthol

smoker could fall into, that really leaves, from the demand perspective, three key questions to answer.

One is, what is the substitution between menthol and non-menthol cigarettes? And it may be helpful to think of the effects of a ban from an overview. If you think, for example, that menthol and non-menthol cigarettes are very close substitutes, what would be the effect of a ban?

Well, if the ban were to eliminate a supply and only create an alternative black market supply that may be charged at a higher price or may be viewed to be more expensive in terms of its full cost, non-menthol cigarettes would become relatively less expensive vis-a-vis menthol cigarettes. And if they were viewed to be close substitutes, you'd have a large shift in demand. In other words, current menthol smokers would largely shift to non-menthol alternatives, and in terms of aggregate smoking effects, you would have very little reduction or no reduction. But you would have a shift from menthol to non-menthol

sales.

On the other end of the spectrum, you could think of a case where the demand for menthol is what an economist would call highly inelastic, meaning that current menthol smokers have strong preferences for menthol cigarettes, in which case even if there was a ban imposed and there was only black market menthols available at, let's say, substantially higher pricing, they would still choose not to shift to non-menthol cigarettes and source the menthol cigarettes on the black market.

The second sort of possibility that can emerge represents the other end, and where the actual world will fall is hard to say. You need to understand what the substitution is between menthol and non-menthol cigarettes to understand whether there'll be no aggregate effect, or if there is an aggregate effect, that would imply a black market would emerge because it would mean that the demand for the menthol cigarettes are highly inelastic. But it also could mean, simultaneously, that there is some reduction in

smoking, and the amount of each of the reduction would depend on that cross-elasticity, and that's part of what we try to evaluate in our study.

This is an overview, so let me get right to it. The first observation, we've reviewed the literature, the economics literature, on the elasticity of cigarettes in general, and that literature estimates that elasticity to be somewhere in the vicinity of negative .3, negative .4, which implies that even if you raise prices of cigarettes, there's not going to be dramatic reductions in consumption. Cigarettes are a product that people consume even in the face of higher pricing.

So the implication of that fact, which is well-supported in the economics literature, is the following, is that if a ban occurs, it's going to have only a small effect relative to the price change, and that small effect would only occur -- as I said previously, the menthol smokers, current menthol smokers, don't view non-menthol cigarettes as alternatives. But the net effect of the change

would be small relative to the price effect that would occur. That's our first finding.

So it's unlikely, in other words, to have a dramatic reduction in overall smoking partly because menthol cigarettes are only a portion of the market, and also because if a black market emerges with an alternative supply, if that alternative supply, even if it's priced 50 percent -- to run through a number, even if it's provided at a cost that's 50 percent higher, it would only be roughly, if you took a negative .3 elasticity, a 15 percent reduction of about 25, 30 percent of the market.

So that would be a 3 or 4 point net reduction, and that's if the contraband price is 50 percent higher than current levels. If it was 25 percent higher, that 3 or 4 percent would be 2 or 3 percent, and so on. And that's really the calibration that you'd have to do to estimate the effect on aggregate smoking from an economics perspective.

The second finding is, from our

preliminary estimates, we find that there's evidence that supports the conclusion that -- and we're looking just to start off with the limitations of our data; we only had access to Newport data. We do not have access to data from other manufacturers.

So for the Newport brand, we found that there is low elasticity. In other words, for the Newport brand, there seems to be only a small amount of shifting that's going on in terms of price changes. And what we looked at is actually wholesale prices, and we looked at buy-downs to retailers. And this touches on something that was presented before.

One of the ways that cigarette companies discount is directly going to the retailer and offering money back. And what we do is we identify months where there were significant changes in Newport's buy-downs, in other words, presumably in terms of retail prices, to see how that affected net flows in demand.

What we observe is that there is

significant shifting between menthol and non-menthol cigarettes, that when Newport aggressively promotes, they appear to take sales away from non-menthol brands, and when they don't aggressively promote, they tend to lose sales. And a lot of those sales go to non-menthol brands.

What that implies in terms of the black market is that there is sufficient demand out there for menthol cigarettes that appears to be -- it shows strong preferences for menthol, and, hence, would likely source from the black market should a black market emerge.

DR. SAMET: Your 10 minutes are done. I think if you could just wind up, please.

DR. FLYER: Okay. So let me go through -- we do a calibration --

DR. SAMET: No. I'm sorry. Just please wind up. Just please end. Thank you.

Let me ask again, those of us on the line had some difficulty with the last speaker in hearing you. Please speak directly into the microphone because if you don't, it becomes very

difficult for us to hear you. And remember that you are limited to 10 minutes.

Sorry to cut you off, and we are of course interested in your presentation, but each speaker is allocated 10 minutes.

Let's see. Mark?

DR. CLANTON: Hello?

DR. SAMET: Mark, go ahead, please.

DR. CLANTON: Yes. My question has to do with any historical data or published data or data coming from these studies that tells us anything about the price elasticity of youth smoking. Presumably -- I mean, there is some general understanding that the higher the price of the cigarettes, the less the initiation and also less likely for kids to continue smoking with a higher price.

But I'm curious about are there any bans on price elasticity?

DR. FLYER: Yes. There is data on price elasticities, and there are a number of studies on youth elasticities. I would reference the

literature itself. There's broad literature on that. And youth, like you say, have inelastic demand. Some believe that demand elasticity is slightly higher than the adult elasticity, although there was an article published about four or five years ago in the Journal of Political Economy that contradicted that result.

But again, the elasticity is well below 1. The industry elasticity is well below 1 for youth, and that's the common result. Whether it lies a little bit ahead of the high -- whether it's slightly higher than the elasticity for adults is something that appears to be the case from the literature.

DR. SAMET: Greg?

DR. CONNOLLY: Are you familiar with the European data that shows countries like Sweden, with the highest price of cigarettes, or one of the highest in the E.U., with a lack of criminal network, has very little smuggling; versus a country like Italy, with a very low cigarette price, or when the study was done, a low price,

but very high criminal activity; and the conclusion of the study that price was not a function, but really it was the presence of criminal activity.

Are you familiar with the 1978 Cigarette Contraband Labeling Act that the federal government, through BATF, enforces?

DR. FLYER: I'm not familiar with the Sweden study. We looked at the Canadian contraband experience. And in Canada, there is a substantial black market that emerged, represents about 50 percent of sales at its peak in Quebec and Ontario; although in other areas of Canada, such as Saskatchewan, the rates were substantially lower.

DR. CONNOLLY: In the Canadian research that you did, did you look at the court documents from New Orleans that implicate senior management in Brown & Williamson with the smuggling activity in Canada?

DR. FLYER: What we looked at are publicly available articles that quantified the

black market in these different areas.

DR. CONNOLLY: Could you look at the role of the tobacco industry in smuggling in Canada and report back to the committee?

DR. FLYER: Okay.

DR. SAMET: Jack?

DR. HENNINGFIELD: Just very briefly, the overwhelming majority of the data that I've seen concerning elasticity is that elasticity for cigarettes is generally similar to elasticity for many other products. And I'm not aware of data that show that menthol somehow is inelastic. If that was true, it would imply that menthol cigarettes are just much, much more addictive than other cigarettes, but I don't think that's the case.

DR. FLYER: Well, let me just say one thing. We did not distinguish elasticity --

DR. HENNINGFIELD: The other comment is, smuggling, it is not simply a function of price, if Dr. Connolly was alluding to this. But in the Canadian situation, for example, it was augmented

by the tobacco industry itself. Those are my only comments.

DR. FLYER: Well, let me just say we never say, or intend to say, that the elasticity of menthol cigarettes are different than non-menthols. That's something that's beyond the scope of the study. The observation we made are on cigarettes in general.

The second comment you have is that that's where most of the uncertainty lies when you're trying to understand what the market will look like in the future, because we don't know exactly what the supply sources would look like, and there has been varied experience. But there has been a substantial amount of information out there that supports the conclusion, when you have arbitrage opportunities in terms of price, you can have substantial markets that emerge and that could fill a large portion of the demand that exists.

DR. SAMET: Melanie?

DR. WAKEFIELD: Thanks, Jon. Just

interesting to reflect on this presentation following the last speaker, where such a large proportion of menthol users would in fact support their product being banned. And I think, along with the tobacco industry arguments that smokers like menthol for taste, this information doesn't quite kind of gel for me in terms of what's likely to happen. It seems like people will -- if it were to go forward, a substantial number of people would use it as a great opportunity to quit smoking.

DR. FLYER: Well, all I can say is we look at -- the difference in the studies is we try to look at market data, which means it's what actually happens, what people do, not what their intents are or what they want. And to the extent that they do things that they may not want, that's something that's beyond the scope of our study.

DR. SAMET: Let's see. Mark, did you have another question?

DR. CLANTON: Hello?

DR. SAMET: Yes, Mark.

DR. CLANTON: Can you hear me?

DR. SAMET: Yes.

DR. CLANTON: Okay. I'm afraid I was cut off completely. I have no idea whether I finished my question or whether that was an answer on the price elasticity issue for use. I don't think so. I'm just looking for whatever was said on that.

DR. FLYER: I'm sorry. Can you repeat the question?

DR. CLANTON: Sure. You're basically saying that menthol cigarettes appear to be fairly price inelastic for adult smokers. What I'm trying to understand is, for example, if there's a ban and then a black market, which produces much higher prices for black market cigarettes, if the price elasticity for tobacco in general and menthol specifically is fairly elastic for kids, it would mean we probably would have fewer kids smoking if it were initiating smoking if there was a ban, and then even a black market for menthol cigarettes.

So my initial question was, is there any

data, historical data, literature-based data, or data that comes from your study, that tells us something about what youth or children would do with respect to whatever their elasticity is for price in tobacco?

DR. FLYER: Okay. There's really two parts. One is -- so I have a clarification. We're not saying that the elasticity for menthol, in terms of switching to non-menthol, would be inelastic. Our best estimates are somewhere around maybe 1.5 for the elasticity of menthol, but with lots of uncertainty associated with that, which technically would not be inelastic demand. In other words, you would have an effect on overall consumption of menthol should the prices go up. That's the first point.

The second point is that that inference is drawn from aggregate data that's primarily accounted for by adult smokers as they smoke the vast majority of cigarettes. So it would not necessarily be a good instrument to measure the elasticity for youth. It's an overall industry

elasticity that's primarily being driven by adult smokers.

DR. CLANTON: Thank you for clarifying that.

DR. SAMET: Thank you for your presentation, and we'll look forward to having a chance to digest it.

We'll move to our next presenter, Gilbert Ross, the American Council on Science and Health. And again, make sure you speak directly into the microphone.

DR. ROSS: I shall do my best.

Thank you very much for the opportunity to discuss menthol with this committee. I represent the American Council on Science and Health. They left my M.D. out, unfortunately. I'd like to say that our organization was founded in 1978, and ever since then we've been in the forefront of anti-smoking education aimed at the public.

This is the 2003 edition of a book we originally researched and wrote in 1996, trying

to -- uh-oh, what did I do?

[Pause.]

DR. ROSS: It's 20 chapters and 200-odd pages long, written by 20 different experts in various medical fields, going through the whole spectrum of the damage to health that cigarette smoking does to the body; each chapter written by an expert, peer-reviewed by about 20 other scholars, with an afterword by Dr. George Lundberg, former JAMA editor-in-chief. I'm proud to be a co-editor of this 2003 edition. That's just to give you some background.

The American Council on Science and Health is a 501(c)(3) nonprofit charitable organization. Financial disclosure, we take money from anybody who'll give it to us as long as it's no strings attached. So send your checks to -- never mind.

When we were following the negotiations leading to the current tobacco regulation bill, the Family Smoking Prevention and Tobacco Control Act, we were wondering why menthol was carved out

of the ban because, as we all know, flavored cigarettes do not really amount to a hill of beans in the plateau of cigarette smoking.

The mantra that young people are attracted to flavored cigarettes, I think, is unsupported by any data. Can you imagine a 16- or 17-year-old kid smoking a cherry-flavored cigarette on the schoolyard? Why menthol was not banned? Menthol is really where the action is in the market.

We assumed at my organization that there was some sort of cynical deal going on to protect tobacco markets. But why would Senator Kennedy and Representative Waxman and all of the public health groups be complicit in such an endeavor?

So we decided to commission a study, a review of the literature, to find out what was the real deal with menthol in cigarettes. And we crafted this approximately 60-page report about mentholation of cigarettes, looking at the science, which is what we do. Our mission is to try to narrow the gap between what people say and

what people think and what actually is supported by the evidence, the science, the data.

We were somewhat surprised to find out that it's not quite so easy to say let's ban menthol, that in fact our conclusions in this report are that there really are no physiological toxicities associated with menthol in cigarettes over and above, of course, the highly lethal effect of the inhaled carcinogens and the addictive nicotine, which are the main problems, respectively.

Nicotine itself is hardly a health problem, but it's a horrible addictive substance, equivalent to cocaine and heroin. The inhaled products of combustion, 4,000 chemicals, God knows how many carcinogens, are what does the damage. Menthol is, of course, a characterizing flavor. It's not quite so easy to say, so let's ban it. I mean, that seems a reflex response; at least it was at first.

But what happens if you ban menthol from cigarettes? That, already, is a subject that's

quite fraught. The previous speaker gave some indication, although I was having a little trouble with the elasticity and the 1.1, and I didn't really understand all of that. But it seems quite clear to me that people who like to smoke menthol cigarettes are really quite devoted to smoking menthol cigarettes, and that if you ban menthol, the chances of creating a black market are substantial.

What would be the benefit? Now, I ask the committee, particularly, to take a step back and say, well, what happens after you ban menthol? Are we going to be improving public health? Will fewer cigarettes be consumed, or will about the same number of cigarettes? Because people who smoke menthol cigarettes actually smoke fewer cigarettes, on the average per day, than people who smoke non-menthol cigarettes.

I believe that banning menthol would lead to a significant black market in the production of menthol cigarettes. These black market cigarettes would be untaxed. Nobody that sells black market

cigarettes asks a kid for an ID to show their age. This has been pretty well documented. When you have major differences, for instance, in tax rates, market smuggling occurs; for instance, between Canada and New York state, having something perhaps to do with the autonomous nation's selling of untaxed cigarettes.

I think that the ban of menthol would be unwise, and I think it might create a new category of war on drugs, similar to the war on marijuana. And given the proclivity of Afro-Americans to smoke menthol cigarettes, I have a fear that it would create a new police dictum to track down people who are smoking menthol cigarettes or selling them, and it would create another racial issue, which is the last thing we need in this country.

And for what? I really don't think that, based upon the data -- and I would urge you to go to our website, acsh.org, and have a look at this paper. But the conclusion that we reach is that our scientific review of the literature does not

support the contention that menthol in cigarettes is particularly more harmful than non-mentholated cigarettes in terms of health effects, heart disease, cancers of any sort.

The issues that have been raised concerning the potential banning of menthol involve issues that are very difficult to measure, such as initiation, cessation. Studies have been mentioned about making it more difficult to quit. The studies that I have reviewed, and I think I reviewed most of these, are fairly inconsistent. Also, they seem to be devoted mostly to people who to go stop-smoking clinics, which is a separate population from the large population.

The RPMI studies by Dr. Hyland, et al., the COMMIT study and the ITC-4 study, seem to show that there was no -- in a large general population, that there was no difference in cessation rates between smokers who smoked mentholated versus non-mentholated cigarettes.

I don't think that's a real issue, either. And even to the extent it is, I think

that you have to weigh the balance of harm versus good to public health that would be done by banning menthol. I believe that more harm would be done by banning it than good.

I have another minute and a half. It's too bad I can't get that gentleman back again. But I'm finished at this point. Any questions?

DR. SAMET: Thank you for your presentation. I would just point out, of course, that much of the process that this committee is involved in now is reviewing the evidence based on all the issues, or many of the issues, that you touched on, not necessarily every single one.

Jack?

DR. HENNINGFIELD: Just very quickly, you have strong opinions and diverse opinions, more harm will be done with a large black market. I'm wondering if on your website or your paper, you have actual data because I didn't hear much data to support that. And in fact, some of what you were saying is in contrast to actual data that we have been presented with.

DR. ROSS: Data about a black market?

DR. HENNINGFIELD: That there would be a large black market created and more harm would be done.

DR. ROSS: That's my opinion.

DR. HENNINGFIELD: I'm curious as to what you meant by more harm would be done to public health -- I'm paraphrasing -- by banning menthol. That's at odds to other presentations that we've had today, except possibly the one just before you. But I'm just wondering, do you have actual data to back up your opinions?

DR. ROSS: No. The only -- I don't. I don't have any data to back up those opinions. I can say that if a substantial black market did appear in menthol cigarettes or self-mentholated cigarettes, that there would be substantial harm to public health, would be done, because there would not be any significant decline in the number of cigarettes smoked, and there would be more availability for young people to buy black market cigarettes since there wouldn't be any regulation.

No, I have no data.

DR. SAMET: Greg?

DR. CONNOLLY: In your presentation, you referenced that menthol was being regulated for characteristic purposes. According to the science, "characteristic" refers to gustatory responses, of which five are in nature.

If we allowed a menthol isomer to be sold that would have the characteristic flavor of menthol but removed its chemosensory properties on smooth receptors, on impact receptors, would you support allowing menthol to be sold as a characteristic flavor?

DR. ROSS: I'm sorry, Dr. Connolly. I do not understand your question.

DR. CONNOLLY: That's too bad.

DR. SAMET: Okay. I think I have no other questions identified from the committee.

DR. ROSS: Would he like to rephrase that in language I could possibly understand?

DR. SAMET: We'll move on to the next presentation now.

DR. ROSS: Thank you.

DR. SAMET: Thank you.

The next presentation is by Bruce Levinson from the Center for Regulatory Effectiveness. Go ahead, please.

MR. LEVINSON: Thank you. I'm Bruce Levinson with the Center for Regulatory Effectiveness. We are a regulatory watchdog that works to ensure federal agency compliance with the good government laws that regulate the regulatory process. We receive funding from virtually every business sector, including the tobacco industry.

The first of the two issues I'm going to discuss today is one of those good government laws, the Data Quality Act. In an exemplary demonstration of the seriousness with which the FDA takes their data quality responsibilities, the agency provided us with a substantive interim response to our request for correction of certain information that was presented to the TPSAC regarding menthol cigarettes.

In their response, the FDA stated that

our petition is under review, that additional time is required to complete their response, and set January 18, 2011 as the target date to complete their work. CRE appreciates the time and attention that the FDA is giving our petition. CRE also requests that the TPSAC defer any decisions regarding the menthol issue until the FDA has completed their work on our data quality petition.

The second issue I'd like to discuss is contraband cigarettes, and the TPSAC is required to consider the impact a contemplated menthol ban would have on the contraband market. Section 907(b)(2) of the Family Smoking Prevention and Tobacco Control Act requires HHS to consider "information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter, and the significance of such demand."

Section 907(e), which is specific to menthol, states that, "The Tobacco Products Scientific Advisory Committee shall address the considerations listed" in the subsection I just mentioned, [b].

To help inform the committee's deliberation, the Center for Regulatory Effectiveness is preparing a major study discussing how a menthol band would likely affect the contraband cigarette trade, the impact of the trade on underage smoking, and the health of adult smokers and nonsmokers.

Another important source of information this committee should consider is the Bureau of Alcohol, Tobacco, Firearms, and Explosives, ATF, part of the Department of Justice. ATF is the federal agency with primary statutory responsibility for combating the illegal cigarette trade under the Contraband Cigarette Trafficking Act.

ATF has substantial information and expertise regarding contraband cigarettes. CRE

recently provided comments in support of an ATF Notice of Proposed Rulemaking on contraband cigarettes. Our comments are available on our TPSAC interactive public docket.

The following three ATF statements from their Notice of Proposed Rulemaking are directly on point with respect to the issues that this committee is statutorily directed to consider, and these are just quotes from the ATF in the Federal Register.

"Contraband cigarettes are more likely to be sold to underage persons than legitimate product."

"The trafficking in counterfeit and contraband tobacco products also poses a serious health risk to our society. There are no standards of production in the counterfeit market. This allows for such things as biological or chemical contamination of the product."

"The legislative history of the CCTA and ATF's investigative efforts over the years have established that organized crime has been involved

in the diversion of legal tobacco products into the illegal market. Moreover, several investigations by ATF and its law enforcement partners have established links to international terrorist groups, including Hezbollah and al Qaeda."

Increased youth access to tobacco cigarettes that pose increased health hazards and financing of international criminal gangs -- those are all issues that the TPSAC needs to weigh when considering a ban on menthol cigarettes. In addition to considering our forthcoming contraband paper, I would encourage you to invite ATF to brief this committee on the potential impacts a menthol cigarette ban would have on the contraband market and the public. Thank you.

DR. SAMET: Thank you for your presentation.

Questions or comments from the committee?

[No response.]

DR. SAMET: Okay. Thank you very much. There are no questions.

MR. LEVINSON: Thank you.

DR. SAMET: We'll move on, then, to Lyle Beckwith with the National Association of Convenience Stores. Go ahead, please.

MR. BECKWITH: Thanks very much. I'm Lyle Beckwith, the senior vice president of government relations for the National Association of Convenience Stores, otherwise known as NACS. NACS is an international trade association representing more than 2,200 retail company members.

The U.S. convenience store industry, with some 145,000 stores across the United States, posts approximately $624 billion in total sales on an annual basis. More than 70 percent of our total membership are companies that operate 10 stores or fewer, and over 60 percent are owned and operated by someone who only has one store.

The number one in-store item for the industry is, by far, tobacco products. This is one of the most regulated products that this industry sells. As a result, NACS has played a

prominent role in the development of United States tobacco policy for the past two decades. Its membership has a deeply vested interest in the outcome of the policy choices that FDA makes.

NACS appreciates that the FDA and TPSAC are under a direct statutory mandate to review and evaluate safety, dependence, and health issues relating to tobacco products. In its work in this regard on menthol, however, TPSAC must consider the practical, real world consequences that a ban on menthol would have.

Now, one of the advantages or disadvantages of going number five in a six-person panel is a lot of what I was going to say has been said or referenced already. So at this point, I'm going to throw away my prepared statement and just address a few of the points that we heard.

There is a black market in tobacco today in this country. I hope there's no debate about that. I have spent 15 years professionally working on legislation trying to close what we refer to as the Native American loophole, tobacco

being sold originally out of brick and mortar stores on Native American reservations, and then as the Internet became more and more prolific, the issue became mail order tobacco sales as well.

Members of Congress didn't really pay attention much because there were only certain areas that were affected by the brick and mortar stores; pockets of New York, Arizona, New Mexico, Oklahoma, Washington state were some of the problem areas. And so when you went to members of Congress who weren't in those areas, it was very difficult to get them engaged to take on the Native American lobby, and so we didn't get very far.

As the Internet got more and more expansive, people started buying more and more tobacco over the Internet. And my standard analysis was, the reason a person went onto the Internet to buy tobacco was for three reasons, two of which were bad.

The first reason they went to buy tobacco on the Internet was because there was a brand that

they wanted to purchase that they didn't have access to. You live in the middle of Montana someplace and you had a strange brand of cigarette you smoked. That's a legitimate use of going on the Internet.

The other two reasons were you went on to avoid taxes or you went on the Internet to avoid age. And the black market that exists today in this country exists because people either want to avoid tax laws or they want to avoid age laws.

Our membership collects and remits taxes on all the cigarette transactions that go on in their stores, and we engage heavily in training of our employees to assure age verification. In addition to my role at NACS, I've been on the board of directors of the We Card Coalition for the past 10 years, and NACS was a founding member of We Card.

I would also point out that since its inception, We Card -- in tracking the Synar rates when there was a 40 percent noncompliance, that rate now, since We Card has been initiated, has

been cut down to 10 percent, with a steady decrease every year. The retailers take their responsibility -- responsible retailers take the responsibility of selling age-restricted products very, very seriously.

Nevertheless, getting back to the black market, I'm not an economist. I'm not a statistician. I'm not a physician. I'm just someone who works with Congress and deals with the retail community, my constituency. And common sense will tell you that if there is a market that exists for an existing product, if it's made illegal, some portion of that market will go to the black market.

There is already a black market, as I said, but that is basically -- nothing has been banned, so everything that is in the black market today is because of price. I firmly believe that if there were to be a ban on menthol, that would be the spark that the black market in tobacco needs to push it into a more burgeoning problem for our country.

My membership loses sales when people go to the black market. In upstate New York, when there's temporary ban placed on reservation sales, the corresponding outlying convenience store sales in tobacco spike 50 percent.

There's already been talk about Canada. My counterpart from the Canadian Convenience Store Association, Dave Bryans, issued a warning to us. He said, "This is a cautionary tale for the United States. The government's inability to curb illicit tobacco is going against public health policies. Our studies concluded that those under 19 who are prohibited from purchasing cigarettes have no trouble getting their hands on cheap, illegal cigarettes."

Clearly, people who are denied the opportunity to purchase their cigarette of choice, if it happens to be menthol, are going to -- some portion of them are going to seek out the opportunity to buy them elsewhere. And the people who will be selling mentholated tobacco out of their trunks are not just going to sell menthol

tobacco. They're also going to sell Marlboros. They're also going to sell fake Marlboros from China.

Who knows what else they're going to sell? Once you're breaking the law, you're breaking the law to make some money, you're going to sell anything you can out of the trunk. I've never sent a We Card training kit to someone selling tobacco out of their trunks. The black market does not check for ID.

So, in conclusion, I just want to say that I'm astounded that there might be a debate about whether or not there's going to be a black market for menthol should it be banned. I just find that to be ludicrous. Of course there's going to be. There already is a black market.

I would also point out that that black market exists right now strictly on Price Point. And I would disagree with those who have spoken earlier to suggest that a black market in menthol would lead to a higher price for menthol.

Indeed, I would project that the menthol,

as all the other products sold in the black market, in the tobacco black market, would be priced well below what the rate is in a traditional store like one of my members because the high tax rate wouldn't be factored into the equation. So what we would have is the ability to buy -- a much more broad infrastructure of black market being established, which would then allow that black market, where it doesn't currently exist, to come in, establish itself, and sell products well beyond the menthol that got it started.

So with that, I'll conclude, and I will be happy to answer any questions, although I don't have statistics. I don't have a study behind me. I can reference some of the studies with which I'm familiar, such as the Canadian Convenience Store Association study, where they actually went and picked up cigarette butts around high schools and concluded that those cigarettes, more than 50 percent of them came from Native American reservations. They weren't even the brands that

you can buy in a convenience store. They were Native American brands.

So happy to answer questions.

DR. SAMET: Thank you for your presentation.

Let's see. Questions. Greg?

DR. CONNOLLY: I was intrigued by your statement that tobacco is one of the most regulated products in America.

MR. BECKWITH: Oh, in our stores, sir. If I said that, I misspoke; in our stores.

DR. CONNOLLY: Okay, in your stores. Now, I might say in your stores, products sold in your stores are regulated by the Federal Consumer Protection Act, by the Federal Controlled Substances Act, by the Federal Toxic Substances Act, and by the Federal Consumer Products Safety Act. But all those laws have exempted tobacco. So when you make the statement it's the most regulated product for your stores, I find that hard to believe, given the fact that five other federal statutes are regulating products sold in

your stores.

MR. BECKWITH: Well, again, I'm talking about this from a perspective of the store owner. Store owners don't have regular stings being done in their stores checking to make sure they're selling the baked beans that are not expired. I mean, our focus on regulatory compliance within the store -- perhaps I misspoke in the way I presented it. But the focus of a store owner in terms of complying with regulatory compliance inside the store is predominately tobacco because that is where they get the most enforcement from -- up until now has been from the state, and now it will be through the FDA. But that is where they receive the greatest amount of enforcement activity.

DR. CONNOLLY: Okay. Just my observation, and I'm congratulating your stores for doing such a good job in complying with other federal statutes that have exempted tobacco. There's finally a federal statute that's addressing tobacco, and I'm sure your stores will

do an equally good job. Thank you.

MR. BECKWITH: Thank you.

DR. SAMET: Thank you, and I don't think I note any other questioners. So thank you for your presentation. We'll move on to the sixth. We do have a seventh presentation; I misspoke earlier.

So our next presenter is Gary Giovino from the School of Public Health and Health Professions University at Buffalo. Gary.

DR. GIOVINO: Thank you all. I don't have slides up yet, but I will introduce myself. I have no relevant financial relationships to disclose. The analyses I'm about to report were supported by the American Legacy Foundation -- I thank them for that -- and were done in conjunction with Biostatistics, Incorporated. Paul Mowery is the principal.

I'm going to talk about patterns of and recent trends in the use of mentholated cigarettes. I'm going to go real fast because I have a lot of information to share.

I do study consequences, patterns, and determinants of tobacco use in individual and policy-level strategies to reduce use. I was involved in studying menthol cigarettes in the early '80s in a clinic population, and I noticed that African Americans were more likely to smoke, and I noticed that advertisements in African American magazines were more likely for menthol.

In the '90s, while in the federal government, I studied Joe Camel and the emergence of Camel in the adolescent market. And in the mid-2000's, I documented an age gradient for flavored cigarettes.

So mentholated cigarettes are at least as dangerous as their non-mentholated varieties, and there are concerns about menthol sweetening the poison. The analyses I will do here will try to clarify some things that I thought were presented in a confusing way at the June meeting.

First, I'll look for an age gradient, using data from the combined 2004 to 2008 National Surveys on Drug Use and Health; and then our study

switching, using data from a cohort study we did, the 2003 to 2005 National Youth Smoking Cessation Survey; and then we'll look at individual data from 2004 to 2008 in NSDUH to look at trends in youth of mentholated and non-mentholated cigarettes in the population as a whole. That's the adolescent and young adult population.

I'm going to go fast through the slides about NSDUH. It is an annual household survey of the civilian, non-institutionalized population age 12 and older. In the 1970s, '80s, and '90s, it was called the National Household Survey on Drug Abuse. There was a major redesign in '99. The sample size was increased to about 70,000 a year. The data collection was switched from paper and pencil interviewing to audio computer-assisted self-interviewing. In 2001 and '2, there were some major changes made, and the menthol question has been consistent since 2004.

Again, it's civilian, non-institutionalized population. The response rates are in the 66 percent range, which is good these

days. And there's over-sampling of 12- to 17-year-olds and 18- to 25-year-olds, so a third of the sample is 12- to 17-year-olds, a third is 18- to 25-year-olds, and a third is 26 and older.

There is some incentivizing that's done. There's some very detailed methods used to maximize response rate and to ensure privacy. And it measures lots of things, including alcohol, tobacco, and illicit drugs.

Tobacco is the first substance measured on the survey, and I need to walk you through a little bit of how it's measured. Again, this is a screen that the respondent would see, and it's basically saying, the next questions are about use of tobacco products. This includes cigarettes, chewing tobacco, snuff, cigars, pipe tobacco.

The first questions are about cigarettes only. Then as respondent enters, "Have you ever smoked all or part of a cigarette?", if the person says yes, they're asked about the first time they smoked part of a cigarette.

Then it says, "Now think about the last

30 days," that is, from October 14th -- there's a fill for 30 days previously, up to and including today. “During the last 30 days, have you smoked part or all of a cigarette?" If the person says yes, they're asked about the number of days they smoked and they're asked about the number of cigarettes they smoke per day.

They're also asked the following: "The next questions are about the brand of cigarettes you smoke. The brand is the name that is on the pack. During the past 30 days, what brand of cigarettes did you smoke most often?" "Most often" is bolded, and they're given a list of 25 of the leading brands.

They either check one of those list, in which case they're sent to verify that, or they say a brand not on this list, number 26 there. If they say a brand not on this list, then they're given 32 of some leading -- the next tier of leading selling brands. If they say one of those brands, then they go to a verification screen, which I'll show in a minute. If they say a brand

not on this list, then they're asked to type in, and I'll show you how that works.

So this now says, "The computer recorded that during the past 30 days, the cigarette brand you smoked most often was True." We just picked True as an example. "Is this correct?" And the person verifies it.

Ninety-six percent of people who said they smoked in the last month gave one of the 57 brands that was listed and had their brand verified. Four percent were asked to type in the name of the brand of cigarettes they smoked most often during the past 30 days, and they said, don't worry about spelling.

Then they say, "During the past 30 days, what type of True" -- again, they fill in "True," whatever brand the person smoked, "cigarettes that you smoked most often," and they say lights, ultra-lights, mediums, or full-flavored.

Then they say, "Were the" -- cig field, True in this case -- "cigarettes you smoked most often during the past 30 days menthol?" Ninety-

six percent of people who smoked in the past month are asked this question. Four percent of people who smoked in the past month are asked this question: "Were the cigarettes you smoked during the past 30 days menthol?" And again, I repeat, 96 percent and 4 percent.

The industry, at least Curtin and colleagues, stated that this was the question that was used on the NSDUH to assess menthol use. It was not. It was a question asked of 4 percent of people. And there seemed to be general confusion in the industry's responses, and they seem to be based on this misperception.

I'm also going to report some estimates from the National Youth Smoking Cessation study. It's a 24-month telephone study of smokers age 16 to 24 years. They smoked one or more cigarettes in the past 30 days, 20 cigarettes in their lifetime, at least. And then there was a baseline survey and a 24-month survey. We had about a 69 percent response rate among age-eligible smokers and households, and the data were weighted.

In that survey, at baseline in 24 months, we said, "During the past 30 days, what brand of cigarettes did you usually smoke, and is the brand of cigarettes that you usually smoke menthol or non-menthol?"

In terms of results, one thing we did do was we used the menthol question, but then we used data from the Nielsen -- the scanning data. And if somebody's brand that they use was basically exclusively menthol, like Newport, Kool, or Salem, we coded them as smoking a menthol brand. And if it was exclusively non-menthol, like Lucky Strike or Winston, we coded them as smoking a non-menthol brand.

So here you can see the first example of an age gradient. This is, overall, everybody from 12 years and older. You see 12- to 17-year-olds are more likely to smoke menthol than 18- to 25-year-olds and then 26- to 34-year-olds, and it seems to level off.

Among males and females, you see again the age gradient for both, 12 to 17 higher than 18

to 25, higher than 26 to 34. For females, the 35- to 49-year-old age group had a higher smoking prevalence of menthol. That's likely due to brand formulations and marketing that likely happened anywhere from during their adolescence to the current time. For males, you don't see that increase in the 35- to 49-year-old group.

Now, if we looked at more precise age categories, just focusing on 12- to 34-year-olds, you see even when we get more precise, you see this step-down age gradient, 12 to 15, 16 to 17, 18 to 21, 22 to 25, and 26 to 34.

Among racial/ethnic groups, again you see the age gradient from 12 to 17, to 18 to 25, to 26 to 34 for non-Hispanic whites. For African Americans, you see a tendency, but there's really a ceiling effect going on there. For Asians and for multiple races, 12- to 17-year-olds are more likely to smoke menthols than any other age group, and for Hispanics you see an age gradient from 12 to 17, to 26 to 34.

Again, when we get into more precise age

categories, again, for non-Hispanic whites and for Hispanics, you see this step-down. For African Americans, it's again a ceiling effect.

Now, the industry in the previous reports thought that you can only really look at people who smoke more than 10 days per month. I disagree, and we looked at people who smoke less than 10 days a month. You see an age gradient again in both 12 to 17, more than 18 to 25, more than 26 to 34. And again, you see it for the more precise age categories. You also see an age gradient for 1 to 5 days and 6 to 9 days.

We see more switching from menthol to non-menthol in our switching study than we do from non-menthol to menthol, although, again, most people didn't switch. And the switching was highest especially for whites and for college grads.

Now, the key to me -- I mean, age gradient matters and switching matters, but the key is, what's the trend and prevalence? And you see among 12- to 17-year-olds a more rapid decline

in prevalence in non-menthol smoking than in menthol smoking. Menthol smoking was -- it was not statistically different. But non-menthol smoking dropped by about half a percentage point a year. The same was true for males and females. And then for 18- to 25-year-olds, the drop on non-menthol smoking was a point and a half per year versus menthol smoking, which actually went up but it was not significant; same for males and females.

So an age gradient does exist. Switching is more common from menthol to non-menthol. And the industry seems to be holding onto the menthol market better than the non-menthol market.

Now, again, to correct the situation, the NSDUH question assessing menthol use is based on brand smoked most often. And the industry also said that trends in the African American 12th grader smoking has not declined in recent years, and African Americans are more likely to smoke -- I'm sorry. The industry said that trends in African American smoking declined in recent years,

and they smoke menthols, so why are you worried about menthols?

But look at what happened in monitoring the future in the last five years. African American trends are flat compared to Hispanic and white trends. And I think that goes against what the industry was saying, and actually raises even more the concern about menthol smoking.

Thank you very much.

DR. SAMET: Thank you, Gary. That was a great deal of information. We're obviously going to need to take a close look at it. But I think some of our quick studies have questions for you.

Melanie?

DR. WAKEFIELD: Yes. Thanks, Dr. Giovino, for your presentation and analysis. It sounded very interesting and helpful.

Can you hear me okay?

DR. GIOVINO: I sure can.

DR. WAKEFIELD: Oh, good. I wanted to just -- you noted that -- it's helpful, I think, that you clarified some differences between the

different surveys that Dr. Curtin and colleagues had presented in the previous meeting, and also some differences in the age categories, and I think that's helpful.

You pointed out that some of the analyses that you've done were more powerful than the method of Dr. Curtin and colleagues. Could you just elaborate on that for us, please?

DR. GIOVINO: Oh, sure. Well, by combining samples, we obviously increased the sample size. We actually redid some analyses of the 2007 data and saw an age gradient if you use 12 to 17 and 18 to 25, which of course are the age years that the survey is designed to look at, but even if you include all smokers.

I very much disagree that you have to limit the sample to people who smoke 10 or more days per month because a lot of the action is going on in people who smoke fewer days per month. And even in the 2007 survey, which is what they presented, we saw an age gradient using their age categories. So I'm not sure why they picked those

age cuts. But even again, when we picked the more precise age cuts, we saw it.

They also used the NHANES survey, but there were like 80 smokers in the 12- to 17-year-old age group in the NHANES survey. So considering that survey the same as the NSDUH survey, I think, is disingenuous.

DR. SAMET: Greg?

DR. WAKEFIELD: Right. Thank you. I just have one more question, which is relating to the cohort study of brand switching. I had noticed that here you're finding that more people are switching from menthol at follow-up than switching from non-menthol to menthol, if that's my understanding of it.

You looked at the data by age category, and some of the individual confidence intervals overlap there. But my guess is that, overall, that's a kind of linear decline with age, that tendency of switching from menthol to non-menthol.

DR. GIOVINO: So now you're talking about the age at baseline data, Melanie?

DR. WAKEFIELD: Yes. So this is in my handout, table 3.

DR. GIOVINO: Yes. I didn't try to find a linear trend there. Really, the data really struck out just for the education group and for white non-Hispanics.

DR. WAKEFIELD: All right.

DR. GIOVINO: You're right. The confidence intervals do overlap in the age groups.

DR. WAKEFIELD: Yes. But it does look kind of suggestive to me as a linear decline. Thank you.

DR. GIOVINO: We can test for that, and we'd be happy to do that and report back.

DR. SAMET: We have a lot of people with their hands up, if you will, and limited time with another presenter. So remember that as you ask questions, please.

Greg?

DR. CONNOLLY: Gary, excellent, and the more information you can provide backing up the data presented to the committee, the better.

Gary, you did speak about the collection of data about brands, but you did not break that out on your presentation. If you collapse that 2004 to 2008, which brand is smoked most predominately by 12- through 18-year-olds?

DR. GIOVINO: Which brand?

DR. CONNOLLY: Yes.

DR. GIOVINO: You don't mean menthol brand; you mean which --

DR. CONNOLLY: No. Which menthol brand is most popular among the young --

DR. GIOVINO: Newport. Newport is most common. Marlboro Menthol was second.

DR. CONNOLLY: Then among the older cohorts over age 35, which is the most popular brand?

DR. GIOVINO: I actually didn't look at that because I was focusing on kids, but -- I can't tell you.

DR. CONNOLLY: I think, if you're looking at that, it's Kool. Do you think there's a correlation --

DR. GIOVINO: Yes. Yes, it would be Kool, Greg.

DR. CONNOLLY: -- in the fact that Newport has a level of menthol that's about 70 percent lower than that of Kool and the attractiveness of the product to young people?

DR. GIOVINO: Yes. I'm familiar that they try to limit menthol to appeal to young people, consistent with the paper by Cummings, et al. and actually Crestlake, et al., showing how they can formulate to appeal to taste sensitivities of young people.

DR. CONNOLLY: Thank you.

DR. SAMET: Jack?

DR. HENNINGFIELD: Gary, it's refreshing to have a strong data presentation. I hope that we'll be able to get much more detail than this in preparing the reports.

One thing I love your comment on, the menthol effect that appears particularly strong in young people looks similar to the effect that you helped document in the '90s with starter smokeless

tobacco products, where the lower dose products designated starters by the industry were more likely to be taken up, but then there was switching away, more likely to be switched away from rather than to. And that was part of the basis for documenting the starter effect.

It looks to me, on the basis of your data, that menthol is not only just an entree to menthol cigarette smoking but to cigarette smoking in general. And I wonder what you feel about that analogy. Are menthols appropriately categorized a starter tobacco product?

DR. GIOVINO: From the data, I think it's very reasonable. Certainly, the NSDUH short report and Jim Hersey's first study are consistent with that. Certainly the age gradient is consistent with that. And what you're saying is consistent with that, with brand formulation.

Certainly, my own experience is consistent with that, if I may venture that, that I experimented with a lot of cigarettes. And the only cigarettes I would let myself smoke were

mentholated, and actually light -- Kool Milds is what I smoked because I didn't -- I thought I was harm reducing, and, of course, I was foolish.

But anyhow, I think what you're saying, Jack, is very consistent.

DR. SAMET: John? Let's see. John Lauterbach? John? Have we lost John?

[No response.]

DR. SAMET: All right. We'll go on. Neal?

DR. BENOWITZ: Thanks for your comment, Gary. That was really very informative.

I want to just follow up with a couple questions about the age gradient. There are two (inaudible) for age gradient; one is the switching and one is the quitting. And I think it's important for us to understand.

Were you able to do any sort of quantitative analysis to see if you could explain all the age gradient by switching as opposed to quitting?

DR. GIOVINO: It's a good question, Neal.

But I haven't done that, and I honestly don't know. You'd have to make a lot of assumptions to do that with cross-sectional data.

DR. SAMET: Let's see. Let me go back. We had lost John Lauterbach.

John, are you on? You had a question before then.

DR. LAUTERBACH: Can you hear me now, Dr. Samet?

DR. SAMET: Yes. Yes, now we can.

DR. LAUTERBACH: The question I had for Dr. Giovino was with the FDA's effort to essentially eliminate underage smoking, underage teen smoking, how does he expect the data trends to go over the next few years?

DR. GIOVINO: I certainly expect -- well, I think what you're asking is, do I think the FDA's efforts will contribute to the continuing reduction in smoking by adolescents. I think that if you're asking me if banning menthol will contribute to that, I think it likely will. But again, that's speculation.

I think what the FDA is doing should be part of a comprehensive tobacco control program. You know, the states are cutting back on their funding, and they should actually be increasing their funding, given all the resources they have available.

But I think the FDA certainly can play a role in educating the American public, certainly with the Secretary's strategic initiative. Young people do need to be educated, certainly with increasing in warning labels and with regulating the product in ways that make the product less appealing. I think the most harm-reducing product is one that's not smoked.

So I would hope that prevalence of smoking among young people continues to decline at least as rapidly, if not more rapidly, than it has been.

DR. LAUTERBACH: That was not -- you didn't answer the question I asked.

DR. GIOVINO: I'm sorry. Then I didn't understand it. Could you repeat -- could you try

to clarify for me?

DR. LAUTERBACH: Okay. The question is, if there are no more starters or current use starters under the age of 18, will all the starting smokers be smoking -- will they start smoking in later years versus younger years? How will your data change?

DR. GIOVINO: Okay. Can you -- it's really breaking up here. I don't think I -- could you say that one more time?

DR. SAMET: I think, Gary, let me -- I'll paraphrase. I think the question is that John sees the number of starter smokers under age 18 as declining, and what are the implications of this decline around -- I guess your surmise is about the role of menthol cigarettes.

DR. GIOVINO: Okay. So if mentholated cigarettes were to go away? I hope I'm not --

DR. LAUTERBACH: No. If you just have very few people starting under the age of 18. You have a lot of data there for 12 to 17, which given the FDA rule, those starters in the future

shouldn't be there.

DR. GIOVINO: Does anybody up front understand? Because it's really --

DR. SAMET: Well, Gary, I think actually -- perhaps we won't spend time on this. I think we'll communicate with you more directly about this. We're about to run out of time.

DR. GIOVINO: Okay. I'm sorry, sir. It's breaking up.

DR. SAMET: Well, thank you. Thank you for your presentation, and we'll be studying the slides in more detail.

DR. GIOVINO: Thank you very much.

DR. SAMET: Our next presenter is Mike Little from the National Black Chamber of Commerce. Go ahead, please.

MR. LITTLE: Good afternoon, and thank you for allowing me the opportunity to speak. I actually wanted to clarify that I signed up as an individual, but I did serve as the past chair of the National Black Chamber of Commerce for six years and became aware of this issue during that

time, and developed some different concerns that are a little bit different perspective than some of those we've heard this afternoon.

I have no relevant financial information to disclose. As I said, I am the past chair of the National Black Chamber of Commerce board of directors. I currently serve on the Maryland Chamber of Commerce board of directors, and I'm a lifetime member of the NAACP.

First I'd like to say that I'm pleased to hear there is so much focus within this hearing being given to the health as it relates to African Americans and those specific dynamics. Many of the things have been said here in a number of ways today, so I'd like to kind of just cut to what my primary concern is.

There are a lot of things that are unique to African American communities, much of it related to levels of income, education levels. And in this case, as we talk about banning, potentially, menthol as it relates to cigarettes, I believe and recognize that it's true, and from

the statistics, that it is a cigarette of choice of African Americans.

The part that seems uncomfortable for me is the fact that certainly I believe and think that there are many indicators that would indicate that if people who want to smoke don't have menthol cigarettes to smoke, that they will smoke non-menthol cigarettes.

So the emphasis that's being put on this issue as it relates to African Americans specifically seems to leave out a number of other issues, as if this is an item for the health of African Americans. And to me, it seems more one that may closely map to those that are generating revenue from menthol cigarettes versus those who generate revenue from non-menthol cigarettes.

As a former smoker, I believe that all cigarettes are bad, and I would certainly support a total ban of cigarette smoking. But I think to isolate something that hasn't been demonstrated or identified as having specific harmful effects, to include African Americans as being a specific

target area as it relates to this issue almost feels as if it's a form of corporate discrimination to me.

So I would ask, in looking at the history of this item -- and I was involved to some degree and did have some conversations with Congress, and particularly the Black Caucus, as this item was discussed over the last few years, in fact -- that I think that if African Americans, like all other residents of our community, don't want to smoke, if they're not allowed to smoke menthol cigarettes, if they choose to smoke, they'll simply smoke other brands.

So I think that there certainly seems to be some business implications associated with the banning of menthol. I would be glad to come back if the agency would like to have support in banning all cigarettes. But if cigarettes are going to be illegal, I don't think that race should ever be used to differentiate and give advantage to some cigarette makers as opposed to others. Thank you very much.

DR. SAMET: Thank you for your comments.

Comments or questions from the committee?

[No response.]

MR. LITTLE: Thank you.

Committee Discussion

DR. SAMET: I guess not. Thank you.

This does conclude the open public hearing portion of this meeting, and we will no longer take comments from the audience.

The committee will now turn its attention to address the task at hand, the careful consideration of the data before the committee as well as the public comments. I would like to thank the public commenters for your input. We value the assistance that you provide.

We now, according to the schedule, are roughly about to run out. There's a conflict between real time and what's on the agenda for discussion. We've covered a lot of territory and maybe are reaching roughly the limits of what people can tolerate in terms of a web-based conference meeting.

But let us sort of recap for a moment what we've done today. And I think we began, really, with an updating from Corinne on where we are with a number of things; from myself on the report, the menthol report writing, and I think the discussion there was useful. There are a lot of items that we're going to be taking on in the now less than two months till our next meeting.

The RTI presentation showed us 11 projects that are in motion, along with the analysis of the Nielsen data. And I think there will be results here that will be relevant if they arrive in a sufficiently timely way for all of the writing groups. And, again, I think in the public hearing that we've just completed, we've heard about results and findings that will be of interest to the committee.

The major task ahead of us, of course, is now the one of examining all this information and synthesizing it, looking to January when we come back --

AUTOMATED VOICE: Our recorder is now

joining.

DR. SAMET: Okay; seems a little late, but --

[Laughter.]

DR. SAMET: Anyway, in any case, the task at hand now is really to get the writing job done in our groups before the January 10th-11th meeting.

So let me see if there are general comments at this point. And let me ask one other thing. Maybe this is to Caryn Cohen. The time of our meeting, we can go over a little bit, or do we turn into pumpkins, or what happens?

MS. COHEN: You can go as late as you feel that you need to.

DR. SAMET: So we can go on for a while. I know some of you -- it's still 2:00 here and I have much scheduled, so I can't go on too long myself. But let's see what else people may want to bring up.

Greg?

DR. CONNOLLY: Could we e-mail comments

to Caryn, Jon, on questions number 1 and 2 and then just circulate them among the group rather than try to get into a discussion now? Because I do think it's -- I think we've got to read these things and provide you some comments and some thought, and I think trying to walk through these at this point in time may not be as productive. And that's up to the prerogative of the chair.

DR. SAMET: Right. We've had some discussion about all this, the questions already.

DR. HUSTEN: Yes. Regarding --

DR. SAMET: We actually have discussed number 2 to a substantial extent at our last meeting.

Caryn -- I guess either Karen, C or K --

DR. HUSTEN: This is --

DR. SAMET: -- in terms of process, if there are additional comments on the questions, the individual -- Greg, I think you're referring to the individual level, the population level questions.

DR. CONNOLLY: No. I just have a lot of

editorial comments that aren't big on --

DR. SAMET: Oh, yeah. I would suggest the editorial thing --

DR. CONNOLLY: You know, I think what I stressed is that we try to stick to the law as closely as possible on population effects, take into account toxicity. The model, I think we all commented on it, thought it was good, but it needed some tweaking. And those are my general comments. But I think the wordsmithing is necessary.

But one other point I would make is in chapter 1 at the very beginning, you sort of set up that we're in a precedent-setting mode here. I'm not sure if we want to make that explicit statement. We are really young in the process here and this is our first shot. And maybe we want to sort of keep open future questions we may face, whether they be modified risk --

DR. SAMET: So let me suggest that it's probably premature to start commenting on particular drafts at this point --

DR. HUSTEN: Jonathan?

DR. SAMET: -- in this venue. I don't think that's the right place to do it. But there will be opportunities to do so.

DR. HUSTEN: Jonathan? This is Corinne.

DR. SAMET: Yes?

DR. HUSTEN: I just want to point out to the committee that the next meeting, we're asking them to come back with their analyses of the strength of evidence. And so I just think it's important that the questions to the committee for this meeting be discussed and agreed upon so that the work groups know their charge and everybody's clear about what they're supposed to be doing and there's agreement about what they're supposed to be doing.

So I just -- there won't be a lot of opportunity to come back and change it because at the next meeting, the groups are expected to report out on levels of evidence.

DR. SAMET: So let me make the suggestion -- and again, we're going to have to do

this relatively briefly -- that we go back to the slides I used, which were really slides that came out of our last meeting, and I think probably just, I would say, reaffirm that everybody understands the approach.

So move away from the model because we'll start tinkering with it immediately, and go down to the slide -- oh, I guess I can do it. Sorry. Let me take this down.

So the proposed approach slide, this one, I mean, which essentially says we're going to be systemic in our review processes and have described evidence synthesis approach and classify the strength of evidence. And then what follows is the statement that we're going to identify the sources of evidence used and we're going to say how we explored them to identify particular studies or documents or surveys. And to the extent that we don't try and be fully systematic -- I mean, for example, the industry documents -- we described how we focused, and certainly our last round of presentations from the UCSF group

described how they -- what they went after in the face of a broad universe of potential documents.

It talks about how we're going to evaluate the evidence, how much there is, the strengths and weaknesses of it, and particularly the key studies. We're going to classify the strength of evidence, and the way we're going to do that was here. And we had extensive discussion about that at our last meeting.

Then this last item, which is on the use of one or more models to assess impact, there would be some conceptual framework relating back to a figure like the one that we've already discussed today, and perhaps a quantitative representation of that figure and those relationships so that we can make some sort of quantitative or semi-quantitative estimates of impact. And we've noted that there are a number of different indicators of impact that might be used.

So I think that goes back -- if we were to, not yet, but go back to those two questions

that were sitting there, that's essentially what they say, that we still like the process by which we said we were going to write the report.

So let's see. We have hands up. I'm going to go backwards. Melanie?

DR. WAKEFIELD: Thank you, Jon. Just for some clarification because I'm a bit of a latecomer to this particular process, my understanding from reading the transcripts of past meetings is that chapters 1 and 2 were going to be fast-tracked. And so my sense is they could be available a little earlier to those of us who are writing some of the other chapters. Correct me if wrong.

DR. SAMET: That's absolutely correct, the goal, yes.

DR. WAKEFIELD: Okay. And then the second question I have is really about the different types of evidence that there are, so balancing peer-reviewed evidence versus non-peer-reviewed evidence. What would be your suggestions about that?

DR. SAMET: Yes. I mean, I sort of alluded to that earlier as well. I think that peer review is one bar, of course, of evidence evaluation. I think that we as a committee really have the obligation to be rigorous in our review of all of the evidence, whether quote "peer-reviewed" or submitted to the committee or based on analysis of survey data by perhaps RTI.

I think we will have to carefully evaluate all lines of evidence. And I think you allude to one of our challenges. We're looking at lots of different kinds of evidence.

DR. WAKEFIELD: Right.

DR. SAMET: And I think, for example, if we're looking at survey data, I think we heard Gary today offering a different, I guess, view and analysis of the survey data, something we had seen analyzed by the industry. And I think there, for example, to understand the differences, we need to go back and look at the documentation ourselves.

So I think the burden is on us to make certain that -- and particularly given what you

allude to, that there are different kinds of evidence -- we have this well sorted out ourselves for the writing groups. And I think particularly we don't have the time, the energy, I don't think, or we just don't have enough people to do a standardized, systematic review of every study that might be considered. But certainly those key studies need careful consideration. And I think your point about the different kinds of evidence is probably something that should go into chapters 1 and 2.

DR. WAKEFIELD: Right. Yes. I think so, too. That would be helpful.

Then just my final comment, really, is although our report is about menthol, there is an awful lot we know about tobacco use and marketing more generally of tobacco that kind of forms a framework, if you like, for understanding some more specific evidence about menthol.

So when we're thinking about the chapter relating to marketing, there's a whole NCI monograph on evidence --

DR. SAMET: Right.

DR. WAKEFIELD: -- that marketing influences tobacco use. So I would be thinking that we would want to draw on that kind of evidence --

DR. SAMET: Sure. Sure.

DR. WAKEFIELD: -- and overlay over the top of it some of the non-menthol-related stuff. Yes.

DR. SAMET: Sure. Absolutely. Yes.

DR. WAKEFIELD: Okay. Just checking that out.

DR. SAMET: Yes. For sure.

Greg?

DR. CONNOLLY: Just a quick comment. I think the model almost suggests we need a longitudinal cohort study of probably 20 or 30 years in length to answer the question, and I'm not sure if that's the intent of the model.

I think there are two key elements to the evidence. One is synthesis, that we don't let one bit of evidence stand on its own and evaluate it,

but it's synthesis of the evidence; and it's purpose of evidence. And I think those two things have to be fleshed out by the subcommittee to be brought back to the main group as we write as quickly as possible so we have clear direction on what we do.

What we're looking at right now, I think, is very good guidance, but the level of specificity that Corinne is looking for, it's not just jumping out right now.

DR. SAMET: Well, it's not Corinne that's looking for specificity; it's us who are going to need it. And the 20- or 30-year cohort is not getting done in the next two months.

Tim?

DR. MCAFEE: Thanks. Well, I think what you've laid out is very, very helpful around making individual, specific determinations relating to the strength of association. And I would just reiterate something that I've heard a couple people mention, and I think has been implied, that -- and whether it would be helpful

to talk about this now more, whether it be helpful to get some more guidance from what FDA needs around this, or if it can be postponed until later.

I think it's going to be very important, basically, to think about what the framework for what a recommendation would be. I mean, I guess my preface would be a little a priori stuff essentially to avoid the situation where we felt that every single one of these associations, for instance, had to be proven in order to make a recommendation that menthol be regulated versus the other extreme, which is if we just got one, that would be sufficient.

So I think Greg had alluded earlier that, well, we can all -- if there's no toxicologic evidence, that's not necessary in order to determine if there's a public health impact. But what if the only thing that comes out of this is that we felt there was a strong association between menthol use and child uptake? Is that sufficient to determine to ban it or not?

I think some of these determinations are really not evidentiary determinations. They're really almost more like the instructions that a judge would give to a jury about how they're supposed to weigh the evidence to make a decision, what are those elements.

So I just think at some point we ought to have perhaps some more explicit conversation about how to make the decision based on what we find in the evidence.

DR. SAMET: Right. So I think, number one -- and I think some of this discussion went on in our last meeting as we framed the level of evidence, levels of evidence, in a way that might be useful for decision-making. I mean, the committee's making recommendations. We understand these will translate into decisions by FDA that the committee -- we've been asked to write a report evaluating the evidence and make recommendations.

So I think what we want to do is provide information and recommendations that will be

useful for decision-making. I think the point about the various questions that we're going to be addressing is one of the other possibly typical -- I don't have an answer t that. I think that's where something like the figure becomes useful for thinking that matter through, and I think we'll have the opportunity to do that.

If we do end up with some useful models for our purpose, that may also help us understand sort of what the implications are of findings that one or another steps in this sort of experimentation, on a sequence, that's been outlined. And also, I know we're going to end up with items where there's uncertainty, there's gaps; and models there would be useful for exploring some scenarios that seem plausible based on the evidence available.

So I think we are definitely going to face these kinds of considerations when we're sitting together in January and meetings following that as we craft our recommendations.

DR. SAMET: Let's see. Mark? Mark, are

you coming on?

[No response.]

DR. SAMET: Maybe not. Let me try again. Mark Clanton, are you on?

[No response.]

DR. SAMET: Okay. Let's see. Mark, are you trying again?

[No response.]

DR. SAMET: All right. Greg, your hand is up?

DR. CONNOLLY: Yes. To Tim's point, the law is clear that we are required to produce a report and consider items, but we don't have to make conclusive findings on each of those items. So I don't see there's a binding of saying menthol does X, Y, and Z, and there's no action to be taken.

So I think the law has given us broad guidance on this one, unlike what the law -- what the Congress told us to do on MRTP products, but they're very, very specific in terms of how we're going to weigh and evaluate the evidence.

The second point is, I don't necessarily like to box ourselves in, in terms of, okay, we're going to ban or not ban. I think there are multiple options that are available to the committee, which I don't know of any and I'm not recommending any. But I think we should leave that open also. But I do not want to see -- I don't think the law allows us to say everything has to be met to make a recommendation or make a report.

DR. SAMET: Let me try Mark again.

DR. CLANTON: Hello?

DR. SAMET: Yes, Mark. Go ahead.

DR. CLANTON: Hi there. I think Greg may have addressed my point. As an extension of the previous question, I'm not sure at all if we need to provide any recommendations in this report. The report, as I understand it, is just that, which is a description of the evidence. And we can certainly offer interpretations of the evidence, but, again, I think it's important that we know up-front whether or not this is something

to report recommendations or this is just meeting the congressional requirement.

DR. SAMET: Okay. Any other comments at this point?

DR. CONNOLLY: Jon, I would just say that the law says we have to do a report and recommendations --

DR. SAMET: Right.

DR. CONNOLLY: -- and we cannot violate a congressional mandate. I'm just saying that the recommendation isn't a yes or no. It's a recommendation, which could be a series of activities. But we do have to do recommendations for the Congress. I don't think we can avoid that.

DR. SAMET: No. And we will soon enough know what they are.

So let's see. Go back to the two questions, please. So just as a reminder -- and, Corinne, you weren't expecting us to say yea or nay, but really to discuss this; is that correct?

DR. HUSTEN: Sorry. My microphone doesn't work unless I keep my finger on the

button.

I just want to make sure that everybody who is working on writing the report is very, very clear about what questions they are to be addressing and the approach they're going to take because, again, at the next meeting, they'll be reporting out.

So just whatever discussion it takes that everybody feels comfortable, that they know what they're supposed to be doing and which --

DR. SAMET: Yes. So as one comment, I think perhaps the questions will, in part, arise as the groups turn to their task. I think Melanie, for example, alluded to one that will likely come up for a number of the groups; how do you evaluate some of the different kinds of evidence; how do we deal with newly done and submitted analyses versus studies that are perhaps from the peer-reviewed literature? I think we will come to those questions and may need some opportunity to discuss such matters further.

But I think between the discussion we had

earlier today and the discussion we had now, and I think the relevant and lengthy discussion we had at our last meeting, I think we have some principles for moving ahead with our writing, and now we need to do so.

Anything else, Corinne, that you want to bring up at this point?

DR. HUSTEN: No.

DR. SAMET: No? Okay. Well, I think we're done. I think this is a useful discussion. I think these meetings are difficult. I think we had a little challenge today with starting up, but maybe we can learn some lessons.

Thank you all for your sticking with the call today, and we'll see you in January. There's nothing like -- I'm not sure why the meeting is not being held in L.A. in January; nothing like going to Washington.

DR. WAKEFIELD: Jon, it's Melanie. I just had one more question --

DR. SAMET: Yes?

DR. WAKEFIELD: -- which is that issue

you just discussed about how we evaluate this different evidence. I mean, it's quite clear that we need to have the same approach for each of the chapters. I don't think each of the groups can come up with their own approach. That wouldn't be desirable --

DR. SAMET: No.

DR. WAKEFIELD: -- to see the different groups starting with a completely different set of assumptions. So that's why I think chapters 1 and 2 will be really very helpful to everybody. And I don't know what the timing is on that.

DR. SAMET: Well, we are trying to get that done, I mean, literally in the next couple of weeks. So I think -- but that's the kind of time frame that you need.

DR. WAKEFIELD: Okay. That's terrific.

Adjournment

DR. SAMET: Yes. Okay. Well, thank you all, and we'll be talking, of course, in various writing groups, and then we'll be face to face in January.

Thank you, and goodbye to everyone.

(Whereupon, at 5:14 p.m., the meeting was adjourned.)